

Dissolution Guide

Our broad range of dissolution testers





Our Dissolution Program USP 1-7

ERWEKA offers dissolution testers for every single harmonized USP/EP/JP dissolution method – starting from USP 1 up to USP 7.



USP methods 1, 2, 5 and 6

We offer a broad range of dissolution testers - from manual testing with the DT 126/128 Light up to the high-volume tester DT 1610 Series.

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| Low-head, high-head & | |
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| DT 720 Series | 10 |
| DT 820 Series | 11 |
| DT 1410 Series | 12 |
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Dissolution Systems

Our semi-automated dissolution systems are available as Offline, Online and On-/Offline Systems for UV-Vis and HPLC analytic.

| Levels of Automation | 14 |
|---------------------------------------|----|
| Dissolution Offline System | 16 |
| Dissolution Online System UV-Vis | 18 |
| Dissolution On-/offline System UV-Vis | 19 |
| Dissolution On-/Offline System HPLC | 20 |



Fully automated Dissolution System RoboDis II

The productivity booster for fully automated, 24/7 non-stop dissolution testing with up to 40 batches.

RoboDis II.....22



Disso.NET 4 Software

Our advanced dissolution software solution Disso.NET 4 controls all our dissolution systems.

Disso.NET 4......26



Pumps

Every dissolution system needs a pump – we offer several options suited to different needs.

Pumps for dissolution systems21



Media Preparation

MediPrep 820 series.....28

We offer the perfect companions to your dissolution tester for fast media preparation and filling of vessels.



USP methods 3/7

RRT 10 BioDis31

The RRT 10 BioDis for automatic dissolution testing of different extended and sustained release dosage forms.



USP 4

USP method 4 is supported by our Flow-Through Cell DFZ II, available as

| USP 4 Flow-Through Cell DFZ II | .32 |
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| Disso.NET USP 4 | .36 |
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Chewing Gum Tester DRT

stand-alone or as a system.

Our dissolution tester for testing of in vitro release of substances into surrounding liquid medium.

DRT.....30



Dissolution Options

ERWEKA offers a broad range of options for all of its dissolution testers and systems.

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USP methods overview

USP method 1 – Basket



Application

- Immediate / Extended and delayed release forms
- Tablets
- Capsules
- Beads
- Floating dosage forms
- Agitation method: Rotating Stirrer

Advantages

- Lots of experience (oldest method, more than 200 monographs in USP)
- No sinker necessary
- pH change possible

USP method 2 – Paddle



Application

- Tablets
- Capsules
- Beads
- Immediate / extended and delayed release forms
- Agitation method Rotating Stirrer

Advantages

- Lots of experience
- Easy to use and robust
- pH change possible

USP method 3 –Reciprocating Cylinder



Application

- Low solubility drugs
- Tablets / Capsules
- Implants
- Granulates & Powders
- Suppositories
- Stents
- Cremes / Dialysis
- Agitation method

Advantages

- Easy pH change
- Hydrodynamic can be influenced by varying dip and rate

USP method 4 – Flow-Through Cell



Application

- Low solubility drugs
- Tablets / Capsules
- Implants
- Granulates & Powders
- Suppositories
- Stents
- Cremes / Dialysis
- Agitation method

Advantages

- Laminar flow possible
- Easy media change
- pH profile possible
- 2 system setups:
- open system (permanent fresh media)
- closed system (long-term tests over many days)



USP method 5 -Paddle over Disk



USP methode 6 -Rotating Cylinder



USP method 7 -Reciprocating Holder



Application

Application

Application

Different holder types:

Advantages

 Standard equipment (USP 2 - paddle can be used)

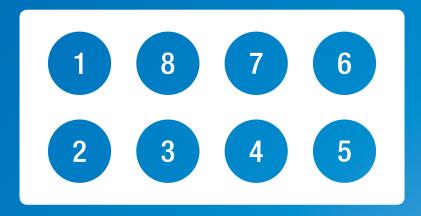
Advantages

- Standard equipment can be used
- Variable volumes
- Big patches useable

Advantages

- Small volumes possible
- Holder can be varied
- Easy pH change

Test station positions



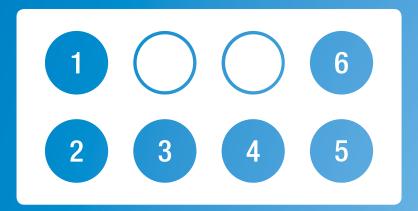
Schematic view of ERWEKA test stations

ERWEKA's dissolution tester can be equipped with 6 or 8 (12 or 14) test stations. Even though all of the testers are offered with a different number of stations, they differ from product line to product line.

The dissolution tester DT 126 light comes with a fixed number of 6 test stations, its bigger sibling, the DT 128 light comes with 8.

The dissolution testers of the DT 720 and 820 series always come with inlets for 8 vessels, which are covered with blinds, if a DT with 6 test stations is ordered.

Dissolution testers with less then 8 stations can be upgraded by ERWEKA service.



Vessel configuration example
DT 726 or DT 826

Positions one through six are usually used for the samples. Position seven and eight are used for reference and blank samples, which are for example required for UV-Vis measurement.



Low-head, high-head und cleaning position

ERWEKA's dissolution testers DT 720 / DT 820 offer two different operating modes which differ by the position of the head, and a third position for cleaning.



Low-head operating mode (LH)

The low-head mode on DT 720 / DT 820 is the standard mode and usually comes in conjunction with a system configuration with automated sampling station (ASS-8). Benefits are the closed vessels and therefore low evaporation.



High-head operating mode (HH)

The high-head mode is best used for manual testing and manual sampling on DT 720 / DT 820. To reduce evaporation, vessels are covered with a cover. Manual sampling is easier in high-head mode. Longer shafts have to be selected on purchasing for high-head mode. In addition, the high-head mode is the only mode of the DT light devices with a fixed head position.





Cleaning position

The cleaning position is the highest position of the dissolution testers' head. It makes cleaning effortless and easy on DT 720 / 820.



Manual dissolution testing, simple and compact

DT light Series

The ERWEKA DT light Series delivers the proven ERWEKA quality in a comprehensive package for a budget for simple dissolution testing with USP method 1, 5 and 6. The DTs are equipped with 6, 8 or 12 test stations and a fixed drive head (high-head), allowing easy access to each 1000 ml vessel.

The shafts can be replaced easily and the unique water bath of moulded PET is equipped with the time-proven ERWEKA water outlet for easy cleaning. The external flow through heater reduces the influence of external vibrations and ensures a constant temperature. Every accessory that comes into contact with the dissolution sample is installed in Germany. Therefore our DT light Series has the ERWEKA made in Germany quality.

All these features make sure that the ERWEKA DT light Series is the perfect entry-level device for the world of dissolution testing.

100%

100% USP/EP/JP compliant



Manual testing



Conical evaporation vessel covers are included

Highlights

- 100 % USP/EP/JP compliant
- Compact design saving lab space
- High-head mode for easy access to the vessels
- Universal shafts with attachments for Method 1,
 2 (paddles included), 5 and 6 available
- Easy cleaning of the water bath and the set-up area
- External flow through heater reduces influence of external vibrations and ensures constant temperature
- Simple control using symbol keypad with LED display for waterbath temperature, RPM (speed per minute) and runtime
- Manual sampling using height adjustable holder for USP sampling points



LED display and symbol keypad for easy control

| Art. No. | Dissolution Tester DT 126/128 Light incl. vessels, paddles, shafts |
|----------|---|
| 19996 | DT 126 Light Dissolution Tester, USP method 2 paddle with 6 test stations |
| 20412 | DT 128 Light Dissolution Tester, USP method 2 paddle with 8 test stations |
| 25025 | DT 1212 Light Dissolution Tester, USP method 2 paddle with 12 test stations |

DT 126 light

Specifications

- High-head with 6 test stations
- Dimensions (width / depth / height): 510 mm / 450 mm / 660 mm
- Weight: 30 kg





DT 128 light

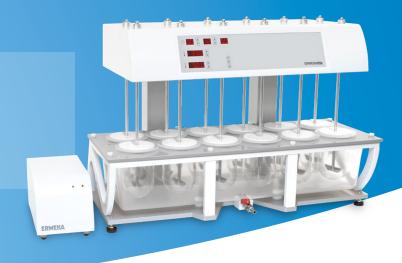
Specifications

- High-head with 8 test stations
- Dimensions (width / depth / height): 642 mm / 482 mm / 680 mm
- Weight: 38 kg

DT 1212 light For high volume testing

Specifications

- High-head with 12 test stations
- Dimensions (width / depth / height):932 mm / 444 mm / 656 mm
- Weight: 60 kg





The ERWEKA DT 720 series has been designed in accordance with USP/EP/JP requirements for testing tablets with 6 or 8 test stations and other dosage forms. It combines proven technology with excellent and user-friendly design. The high-head and low-head operating modes offer highest flexibility. The tester can be used as a standalone device as well as a dissolution online analysis system equipped with an automated sampling station, operated via the ERWEKA Disso.NET 4 software.

The manual lifter column with gas-strut support allows effortless and rapid lifting and lowering of the drive head in just a few seconds. Tablets, pellets and other dosage forms are inserted in the drive head via the manual tablet drop magazine. Samples are withdrawn for analysis through special, membrane sealed sampling openings inside the drive head. The evaporation is less than one percent during 24 hours (37° C, 50 rpm, 1000 ml).

The extensive use of carbon fibre eliminates metal usage and therefore reduces the risk of corrosion to a minimum. Test run parameters can be documented via the USB-A printer interface (optional).

| Art. No. | Dissolution Tester DT 720 Series |
|----------|--|
| 18316 | DT 726 (LH/HH) 1000 ml Dissolution Tester with 6 test stations |
| 18318 | DT 728 (LH/HH) 1000 ml Dissolution Tester with 8 test stations |



100% **USP/EP/JP** compliant



methods 1, 2, 5 and 6



Online System with UV-Vis or **HPLC**



High-head and lowhead mode





ERWEKA DT 820 series with 6 or 8 test stations offers advanced intelligence and features for stand-alone operation or for control of a complete dissolution offline system with automatic sampling. It allows storage of up to 60 product test methods.

The DT 820 series can be equipped with 6 or 8 test stations and be used in high-head or low-head mode. It offers an visual traffic light to show USP qualification requirements compliance, a conical evaporation cover as well as an external temperature sensor for checking the water bath.

The water bath is designed for easy access and cleaning and is made of non-leaking PET. Centering rings ensure correct position of vessels and stability for withdrawal of samples.

Highlights



100% USP/EP/JP compliant



Direct control of offline system possible



USP methods 1, 2, 5 and 6

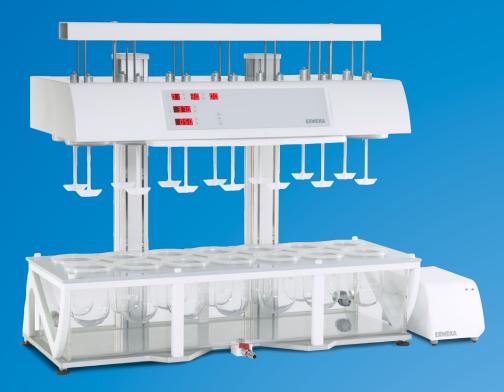


High-head and lowhead mode

| Art. No. | Dissolution Tester DT 820 Series |
|----------|---|
| 18324 | DT 826 (LH/HH) 1000 ml Dissolution Tester with 6 test stations |
| 18326 | DT 828 (LH/HH) 1000 ml Dissolution Tester with 8 test stations |

Dissolution Tester

DT 1410 Series



The DT 1410 series is based on the proven DT 720 series and can be configured for 12 or 14 test stations arranged in two rows.

The DT 1410 provides the possibility of performing one test with 12 or 14 tablets or two tests parallel with 6 or 7 tablets. The substantial advantage is that two USP tests can be carried out with one test bath at equal test conditions. Besides, the unit is offered with various vessel sizes (400 ml, 1000 ml) and is available with high-head (maximum access) and low-head (low-evaporation version; for automation) mode.

The DT 1410 series is made for users with generic products or high capacity in mind. Due to the configuration, the device allows to run two different batches of the same product or two different products with the same dissolution monograph at the same time.

Art. No. Dissolution Tester DT 1410 Series 18319 DT 1412 (LH/HH) 1000 ml Dissolution Tester with 12 test stations 18321 DT 1414 (LH/HH) 1000 ml Dissolution Tester with 14 test stations

Highlights



100% USP/EP/JP compliant



USP methods 1, 2, 5 and 6



Test 12/13/14 tablets or 2 batches with 6 or 7



High volume Online System with UV-Vis or HPLC



Manual and semi-automated

Dissolution Tester

DT 1610 Series

The ERWEKA DT 1610 series offers advanced intelligence and features for stand-alone operation or for control of a complete dissolution offline system with automatic sampling. It allows storage of up to 60 product test methods.

The DT 1610 series can be equipped with 12 or 14 test stations arranged in 2 rows, which can be operated in high-head and low-head mode.

It offers an OQ traffic light to show USP/EP compliance as well as an external temperature sensor for checking the water bath temperature. The water bath is designed for easy access and cleaning.

| Art. No. | Dissolution Tester DT 1610 Series |
|----------|--|
| 18328 | DT 1612 (LH/HH) 1000 ml Dissolution Tester with 12 test stations |
| 18330 | DT 1614 (LH/HH) 1000 ml Dissolution Tester with 14 test stations |

Highlights



100% USP/EP/JP compliant



USP methods 1, 2, 5 and 6



Test 12/13/14 tablets or 2 batches with 6 or 7



Direct control of high volume offline system



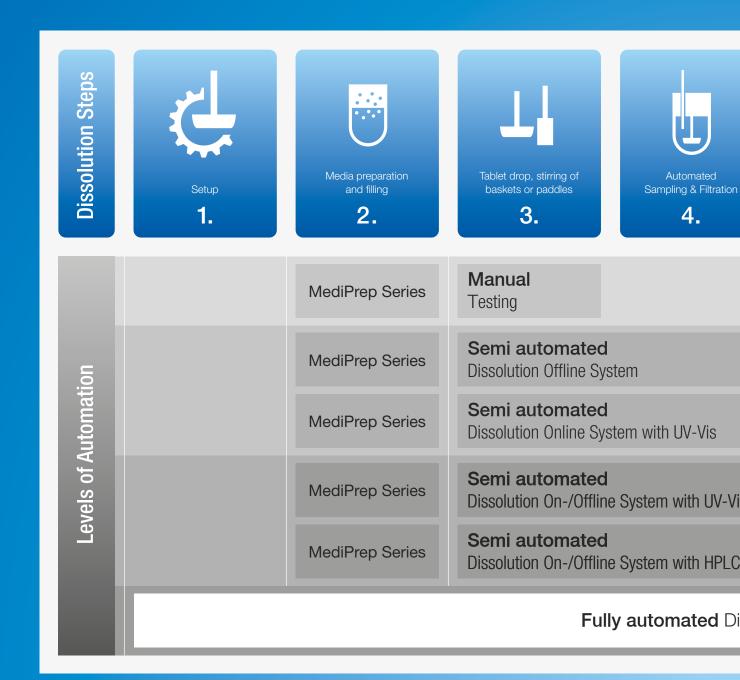
Easy cleaning



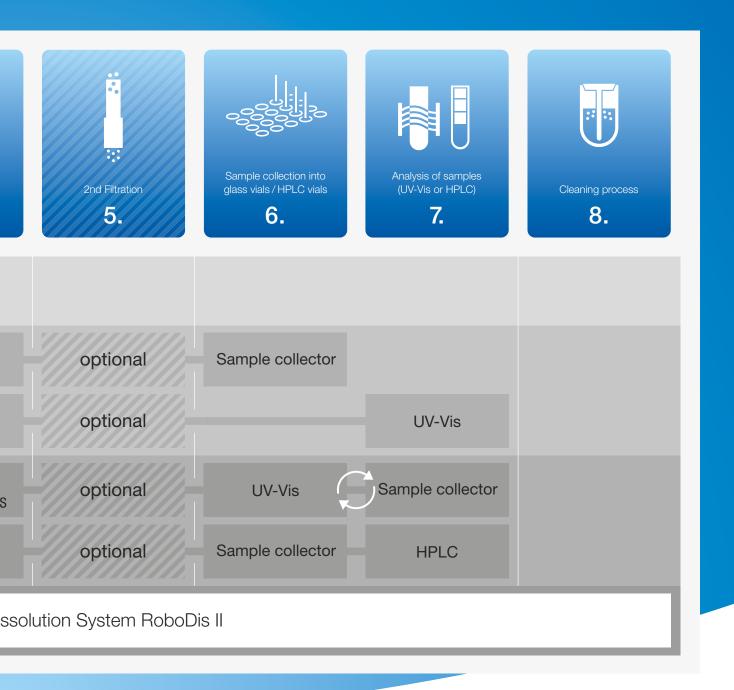
Levels of Automation

ERWEKA offers several products for different types of automation levels. The semi-automated Dissolution Offline System for automation of three steps of the dissolution process or a semi-automated Dissolution Online System are perfect entry-level systems into the world of 100% USP/EP/JP,

automated testing. Our Dissolution On-/Offline System with UV-Vis or HPLC analysis automates five steps of the dissolution process. In addition with a MediPrep the media preparation can also be automated.



For fully automated 24/7 testing and 100%-reproducibility of all tests, we offer the RoboDis II - a real productivity booster with fully automated dissolution testing of up to 40 batches including setup, media preparation and cleaning automation.



Semi-automated dissolution testing

Dissolution Offline System

The ERWEKA Dissolution Offline System is the ideal semi-automatic solution for dissolution testing with automated sampling and subsequent sample storage for later analysis. The system is controlled by a DT 820 series dissolution tester with advanced intelligence.

The DT 820 series equipped with i-Version comes with integrated intelligence for controlling independently the offline sampling system, which consists of an auto sampling station ASS-8 connected to the DT, a pump (peristaltic or piston) and the sample collector of the FRL-series for storing the samples in glass tubes or sealed HPLC vials.

This configuration does not require an additional PC or any software and therefore saves space, money and last but not least software validation work.

Highlights



100% USP/EP/JP compliant



USP methods 1, 2, 5 and 6



Direct control of the complete system by DT 820



Sample collector FRL 6/7/854

| Art. No. | Dissolution Offline System |
|----------|--|
| 25371 | Standard Offline Dissolution System with IPC 8 for DT 826, FRL 654 |
| 25370 | Standard Offline Dissolution System with IPC 8 for DT 828, FRL 854 |
| 25376 | Standard Offline Dissolution System, IPC 16 f. DT 1612, FRL 654-22 |
| 25378 | Standard Offline Dissolution System, IPC 16 f. DT 1614, FRL 754-2 |

High volume testing with sampling collector







ERWEKA

DT 820 Series

ERWEKA dissolution testers of the DT 820 series are 100 % compliant to USP methods 1, 2, 5 and 6. By default the Offline System is equipped with a DT 820 in low-head mode and can be also optionally operated in high-head mode.

PVP 820 Series

The practically maintenance-free piston pump transports the test medium with high precision and pressure via eight channels to the compact sample collector of the FRL 854 series. Peristalsis pump optionally available.

FRL 854 Series

The sample collector FRL 6/7/854 offers a space-saving footprint and a precise dosing for up to 26 rows with 8 channels. This is also available for 12 and 14 digit DTs with 2 rows of filling needles.



The highlights of the new

Dissolution Online System UV-VIS

The ERWEKA Dissolution Online Systems are the perfect, semi-automatic solution for dissolution testing with integrated UV-Vis online analysis. The DT 720 with automatic sampling station ASS-8 transports freshly taken samples via a pump directly to the UV-Vis analysis. The samples are analyzed directly and the data is evaluated and saved using our advanced Disso.NET software.

With the help of the Thermo Scientific™ Evolution 350™ Double-Beam Spectrophotometer that we recommend, 5-minute cycles in the 200 nm to 350 nm range, which is important for dissolution tests, can be tested and evaluated with high efficiency. In connection with the maintenance-free pump PVP 820, the customer can trust on highest reliability in half-automatic dissolution testing inclusive UV-VIS Analysis.



100% USP/EP compliant half-automatic dissolution testing



USP Method 1, 2, 5 and 6



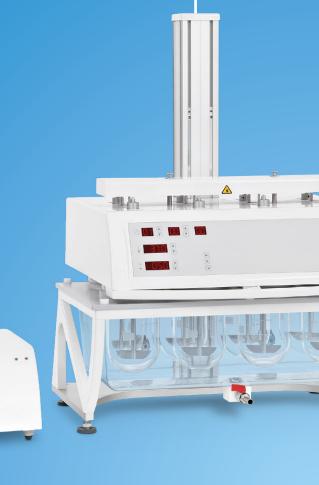
Fast Thermo Scientific™ Evolution 350™ Spectrophotometer for 5-min. cycles



Completely software controlled by Disso. NET with integrated control of the Evolution 350 TM

| Art. No. | Dissolution Online System UV-Vis with IPC |
|----------|--|
| 26932 | UV-Vis Online System with Evolution 350, IPC 8 for DT 72x + Disso.NET 4 |
| 27028 | UV-Vis Online System with Analytic Jena Specord 210, IPC16 for DT 141x/DT 161x |
| 27030 | UV-Vis Online System with Shimadzu 1900, IPC 8 for DT 72x + Disso.NET 4 |
| 26934 | UV-Vis Online System Evolution 350, PVP 820 for DT 72x + Disso.NET 4 |
| 26983 | UV-Vis Online System with Analytic Jena Specord210, PVP 1420 for DT 141x/DT 161x |
| 27031 | UV-Vis Online System with Shimadzu 1900, PVP 820 for DT728 + Disso NFT 4 |

ERWEKA





Dissolution Tester DT 728

The ERWEKA DT 728 is the perfect dissolution tester for the ERWEKA DT online system. The DT 728 ensures absolutely reliable test results that the user can rely on. 100% USP/EP compliant, in the usual robust ERWEKA quality and with integrated automatic sampling station ASS-8 and automatic tablet drop.

High-precision pumping with the PVP 820

With the maintenance-free PVP 820 piston pump with high pressure, the samples are transported precisely from the dissolution tester to the Thermo Scientific $^{\text{TM}}$ Evolution 350^{TM} Photometer.

Complete control with Disso.NET

The Windows software Disso.NET completely controls the entire dissolution system, manages methods with tests and generates the associated reports. The software tracks all changes that are made using the integrated 21 CFR part 11 compliant audit trail. Thanks to the full integration of the Thermo Scientific Evolution 350, the UV-Vis evaluation takes place directly in the Disso.NET - so the user has all the data of the dissolution test in one place. The USP / EP photometer qualification can also be done on request.

Thermo Scientific™ Evolution 350™ UV-Vis Photometer

The Evolution 350^{TM} is a fast double-beam photometer with xenon flash from Thermo ScientificTM. It is completely USP/EP compliant, offers selectable ban width (0.5 - 4.0 nm) and enables 5-minute cycles with spectra between 200 nm and 350 nm. It is completely integrated in the Disso. NET from hardware conrol up to data evaluation and can be qualified on request.



ERWEKA





The highlights of the

Dissolution On-/Offline System with HPLC

The ERWEKA Dissolution HPLC On-/Offline System is the semi-automatic solution for 100% USP/EP/JP compliant dissolution testing with HPLC online analysis. Up to 5 of 8 dissolution steps can be automated by combining one of our highly qualified DT 720 series dissolution testers with devices for CTC sampling and online HPLC chromatography. The entire system with all components is controlled by our easy-to-use Disso.NET software.

For filtrations up to 0.22 μ m, our automated filter changer AFC 825 can be used in combination with our maintenance-free PVP pump. In addition, to a precise and simple control of the entire system, Disso.NET offers an accurate recording of the whole test process, from the automatic recording of the sampling time up to the recording of the temperature and rotation speed in each vessel (= Documentation of all system operations, audit trail).





Available from



100% USP/EP/JP compliant



21 CFR Part 11 conform in conjunction with Disso.NET software



PAL RSI sample collector and sample storage for HPLC analysis



5 of 8 dissolution steps are automated

Dissolution Tester DT 720

Our dissolution tester of the DT 720 series is 100% compliant to USP methods 1, 2, 5 and 6 and can be operated in high-head as well as low-head mode.



PVP 820 Pump

The test medium is transported with high precision and pressure via eight channels to the automated filter changer AFC 825 by the practically maintenance-free piston pump. In conjunction with the AFC 825, it enables a filtration with up to $0.22 \mu m$ flat membrane filters.

Double filtration with AFC 825

In case of a HPLC analysis it is recommended to perform a double filtration, to avoid contamination or damage of the HPLC column due to particles, thus improving the accuracy of the HPLC analysis. The high-precision, practically maintenance-free PVP pump in combination with the automated membran filter changer are particularly suitable for this purpose. APC 825 for 6 or 8 stations.



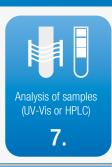






5.







Dissolution On-/Offline System mit HPLC

optional

HPLC sample collection & analysis

With the HPLC sampler the samples can be collected (and cooled) and injected automatically in the HPLC system. Analysis and evaluation are done by the HPLC analysis device and the associated analysis software (different providers: Agilent, Shimadzu, Waters etc.).







| Art. No. | On-/Offline System HPLC |
|----------|---|
| 27029 | HPLC On-/Offline Dissolution System with PVP 820 piston pump with RSI sampler |
| 25024 | Stand for HPLC sampler above Spectrophotometer |
| 18482 | Dual system upgrade for connecting two DT Dissolutiontesters DT 720 |
| 18499 | AFC 825 - 16 V membrane filter change system for DT 728 |

HPLC-Analysegerät nicht in Systemkonfiguration enthalten! (Unterstützung verschiedener Hersteller)

HINWEIS

ERWEKA Systems

Dissolution On-/Offline System UV-Vis



The ERWEKA Dissolution UV-Vis On-/Offline System is the ideal system configuration for spectrophotometers. With the connected PC, the On-/Offline System can be conveniently controlled via our advanced Disso.NET software. Moreover, the software offers full control over all components and storage of all test results.

After analysis has been completed, the samples are comfortably stored by our very own sample collector FRL 654/754/854 for later HPLC analysis or as reference standard.

Highlights



100% USP/EP/JP compliant



Controlled by Disso.NET

| Art. No. | Dissolution On-/Offline System UV-Vis |
|----------|--|
| 26936 | UV-Vis On-/Offline Dissolution System, Evolution 350, IPC-8 DT 72x/82x |
| 27034 | UV-Vis On-/Offline Dissolution System Shimadzu 1900, IPC, 8 channel for DT 72x |
| 27036 | UV-Vis On/-Offline Dissolution System Analytic Jena Specord 210/16 for DT 141x |
| 26939 | UV-Vis On-/Offline Dissolution System Evolution 350, PVP 820, for DT 728 |
| 27035 | UV-Vis On-/Offline Dissolution System Shimadzu 1900, PVP 820 for DT 728 |



USP methods 1, 2, 5 and 6



Advanced UV-Vis analysis



Sample collector and storage

| Big volume testing with DT 141x and A | nalytik Jena Specord 210/16 |
|---------------------------------------|-----------------------------|
| | - <u></u> |
| | Disso.NET |

UV-Vis On/-Offline Dissolution System Analytic Jena Specord 210/16 PVP DT 141x

27042

Overview

Pumps for Dissolution Systems







Peristaltic pump

ERWEKA piston pumps

| Pump | IPC 8 / 16 | PVP 620 / 720 / 820 | PVP 1220 / 1420 |
|-----------------------------------|--|--|--|
| Channels | 8 or 16 | 6 or 8 | 12 or 14 |
| Valves | | | |
| Accuracy | +/- 0.5 ml | +/- 0.5 ml | +/- 0.5 ml |
| Media replacement | | | Standard |
| Double filtration (optional) | Only when first filtration with poroplast filters. No media replacement possible when double filtration. | No media replacement possible when double filtration | No media replacement possible when double filtration |
| Required type of sample collector | FRL 624 / 724 / 824 | FRL 624 / 724 / 824 | FRL 624 -2 / 724-2 / 824-2 |
| System compatibility | DT Offline / DT Online DT On-/Offline | DT Offline / DT Online DT On-/Offline | DT Offline / DT Online DT On-/Offline |
| Advantage | Basic pump possible with DT 14x/16x, needs regular replacement of tubing | Filtration down to 0.22 µm for flat membrane filters, Best choice for fully automated dissolution systems | Filtration down to 0.22 µm for flat membrane filters, low maintenance even at high throughput, Best choice for dissolution systems |

Fully automated: RoboDis II

The flexible specialist for R&D

Many types of dosage forms

The RoboDis II can handle several types of dosage forms. No matter what you use - tablets, granulates or powders - the RoboDis II is the ideal, flexible and fully automated dissolution system for all your usage needs. It even handles Japanese Sinkers with a size of up to 34 mm with ease!

Versatile filtration

Filtration with the RoboDis II has no boundaries - inline poroplast filters, membrane filters down to 22 μ m and even double filtration are supported.

pH Half Change and pH Full Change (USP methods A & B)

The fully automated ph change (both half and full possible) is supported by the RoboDis II. Just configure your method using the powerful Disso.NET software and run your test – the RoboDis II will automatically take care of the rest.

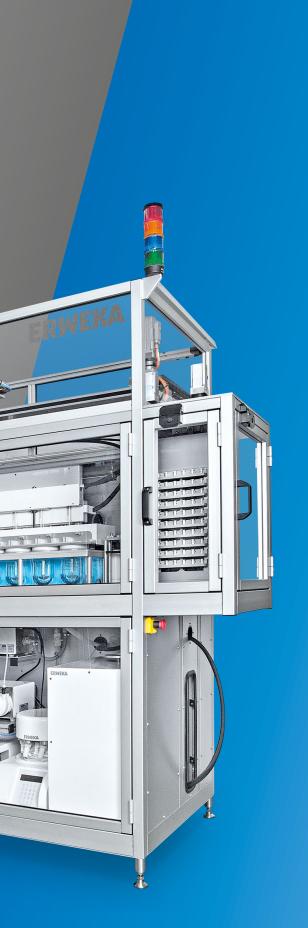
Broad range of analytics available

RoboDis II supports a broad range of analytical devices. UV-Vis spectrophotography, chromatography using HPLC or even a combination of both – the RoboDis II handles and controls all of them.

6 reference standards

Mandatory in R&D: Flexible reference standards for quick testing of several formulations. Thanks to an integrated standard changer system, the RoboDis II handles them with ease.





The Produtivity Booster for Quality Control

Planned productivity with 10 or 40 batches

Productivity can be easily scheduled with the RoboDis II. For example, the system can autonomously handle up to 40 batches during the weekend and then present all the results to the laboratory employee on the following workday for evaluation. With video recording and time-lapse function, a visual inspection of the completed test process is possible afterwards.

High volume - 40 batches

Testing, testing, testing - that is what the RoboDis II does best. The 40 batch option allows volumes that are usually only matched by a multitude of semi-automated systems, demanding a lot more laboratory space and staff then ERWEKA's RoboDis II. Real productivity gain!

Parallel approach

The RoboDis II is following a parallel test approach: Tablet drops, sampling and emptying of the vessels are all done in parallel.

Robotic precision & integrated error control

Every dissolution step is fully automated and is completely tracked by the software itself (SST). This means, that all tasks performed by the RoboDis II during a test are identically repeated in the next test, thus removing the human error factor completely. The system offers highest reliability and allows the laboratory employees to concentrate on the analysis of the provided data.

Space-saving footprint

To match the RoboDis IIs productivity with semi-automated systems, at least three Dissolution Online Systems and operators are needed to perform 10 batches per day. Convince yourself!

The Productivity Booster

RoboDis II

The fully automated dissolution system is already used in quality control and R&D by several multinational companies and has brought a huge increase in productivity. It fully automatically handles 10 or 40 batches of dissolution testing USP method 1 basket or method 2 paddle in a parallel approach, therefore enables very short sampling points of 5 minutes, depending on product and method. As all ERWEKA products, the RoboDis II works 100% conform to all harmonized pharmacopoeias in every aspect.

All steps of the dissolution process - media preparation, filling, setup of dissolution tester, testing, automated sampling, online analytics (UV-Vis or HPLC) and the whole cleaning process are performed automatically and without the need of user intervention. The whole system is controlled by the ERWEKA Disso.NET software, from the robot arm to media preparation and analytic devices.

Supported by several integrated System Suitability Tests (SST) and light sensor checks, this system runs absolutely precise and reliable, minimizing human error. It is human error proofed so to say.

Highlights



100% USP/EP/JP compliant



Controlled by Disso.NET



USP methods 1 and 2



System Suitability Tests (SST)



10 or 40 batches in one test run



Video monitoring



Online UV-Vis or HPLC analysis



pH half change or full change



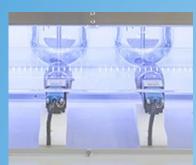
Vacuum degassing



10 or 40 Batch sample magazine for continuous testing 24/7.



Continuous verification of processes with controlling sensors.







Simultaneous tablet insertion allows high accuracy of processes.



pH change in accordance with USP Method A (Half Change) and optional USP Method B (Full Change) possible.





Different tools for different applications are available.



Automatic cleaning and result checks of the cleaning process (SST).

The new

Disso.NET 4 dissolution software

The ERWEKA Disso.NET 4 is the perfect 21 CFR Part 11 compliant companion to all our Dissolution Systems, ranging from Dissolution Offline over Online to On-/Offline Systems up to the fully automated RoboDis II system.

The software helps you with standard dissolution jobs, easily handles qualification tasks and provides control over each single function and connected devices (e.g. dissolution tester with UV-Vis spectrophotometer). After finishing those tests, Disso.NET creates extensive reports with corporate logos for PDF-file export or exports your results in XLS or XML.

Our extensive Audit Trail according to latest 21 CFR part 11 thoroughly documents all changes done to the system (what, who, when and why) and can be easily searched and filtered by the Audit Trail Viewer.

Supports Dissolution Systems, RoboDis II

The Disso.NET 4 supports all ERWEKA Dissolution Systems and the fully automated RoboDis II.

Full Audit Trail according to 21 CFR Part 11

The Audit Trail feature is implemented throughout the whole software, tracking each and every change (What, Who, When and Why). If data is changed by the user (e.g. when editing methods), the software requires a reason entered by the user. In combination with our easily search- and filterable audit trail viewer, changes to the system and its data can be easily traced back to its origin and originator. With Disso.NET 4, it is not possible to delete data from the system to maintain data integrity.



Full Audit Trail according to 21 CFR Part 11



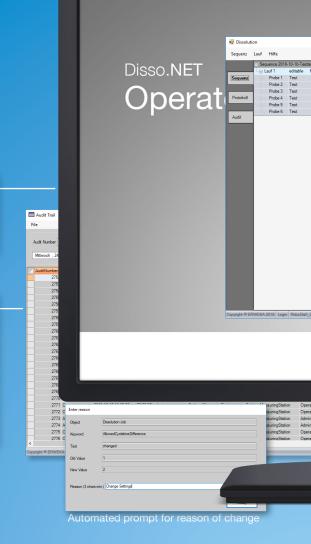
MS SQL Database



Support for USP methods 1, 2, 5 and 6



Management |



Easy documentation with industry proven features

The documentation features of the Disso.NET 4 are vast: Easily generate reports about products, tests, audit trail, measurement conditions, UV-Vis and HPLC workflows and export data as PDF, XML and Excel format.



Advanced media preparation of 16 liters in less than 25 minutes

MediPrep Series

The ideal companion for our dissolution systems

The MediPrep series offers quick and easy preparation of up to 16 liters dissolution media in less than 25 minutes. In a single pass, the media for dissolution tests can be precisely mixed, heated, degassed and gravimetrically filled into vessels. Foaming media like SDS (Sodium Dodecyl Sulfate) can also be used.

Gravimetrically controlled filling can be done at the integrated dosing port or with the optional remote filling hand directly into the vessels.

The MediPrep 820 provides one inlet for premixed media and one outlet for waste water. In comparison the MediPrep 1622 offers two additional inlets for media concentrates or premixed media. To prevent cross contamination, an automated cleaning procedure is integrated.

Up to 3x faster than manual media preparation*

The devices of the MediPrep family allow up to 3x faster media preparation in comparison to a manual approach. Even better - while MediPrep does all the media preparation on its own, the laboratory employee can focus on other more imporant tasks, thus increasing productivity.



100 % USP/EP compliant filling



GLP/GMP compliant documentation



Up to 14 I 1 % SDS-containing medium with MediPrep 1622



Memory for 50 users with three different access levels



Memory for 100 methods



Available with 8 liter and 16 liter tank

| Art. No. | MediPrep Series |
|----------|--|
| 18605 | MediPrep 820 (230 V) 8 liters with one inlet |
| 27014 | MediPrep 820 (115 V) 8 liters with one inlet |
| 25813 | MediPrep 1622 (230V) 16 liters with two inlets |
| 26943 | MediPrep 1622 (115V) 16 liters with two inlets |

*compared to manual media preparation



ERWEKA





Complete GLP / GMP documentation

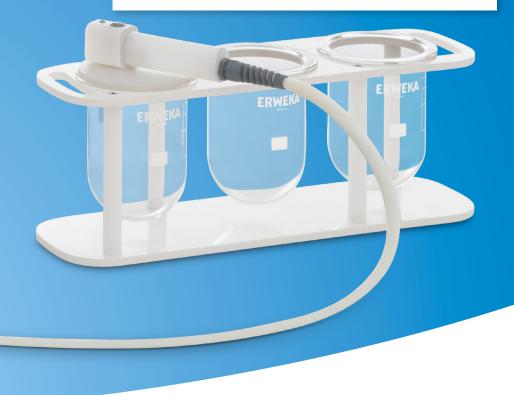
The ERWEKA MediPrep logs all important information according to GLP/GMP standards that arise during media preparation and can easily assign the data to a batch ID on the report.

Highly precise filling

Thanks to gravimetric filling, the MediPrep works with the highest precision that the user can always rely on.

Integrated cleaning procedure

Thanks to the integrated cleaning procedure, the MediPrep can automatically clean the built-in media container and all tubing. This leaves no residues and the user can easily prepare the next medium without wasting time.



Chewing Gum Tester **DRT**



Highlights



Testing for in vitro release of substances from samples into surrounding liquid medium

The ERWEKA DRT is the perfect device for testing of in vitro releases of substances from chewing gums and other dosage forms, that have to be masticated, into the surrounding liquid medium. The vertical up and down strokes of the lower jaw in combination with a revolving movement of the upper jaw provide ideal mastication of the chewing gum and at the same time an agitation of the test medium.

For manual sampling, emptying and cleaning the lower jaw with the test cell can be lowered into a down position, so that the chewing process stops.

The test cell, the upper and lower jaw can then be easily removed. A water circulation system controls and regulates the water temperature in the test cell around the media.

The chewing gum test apparatus is used to masticate gums and then analyzes the speed at which various substances leave the gum (release). In addition, the device is very helpful for developing candy chewing gums, but it can also be used for unusual purposes such as testing of snuff bags.

| Art. No. | Chewing Gum Tester DRT |
|----------|--|
| 18620 | DRT 1 Chewing Gum Tester (1 test station), incl. manual |
| 18621 | DRT 2 Chewing Gum Tester (2 test stations), incl. manual |
| 18622 | DRT 3 chewing Gum Tester (3 test stations), incl. manual |
| 18623 | DRT 4 Chewing Gum Tester (4 test stations), incl. manual |
| 18624 | DRT 5 Chewing Gum Tester (5 test stations), incl. manual |
| 18625 | DRT 6 Chewing Gum Tester (6 test stations), incl. manual |

Multiple media pH change dissolution testing for USP 3 and 7

RRT 10 BioDis

With the ERWEKA RRT 10, automatic dissolution testing of different extended and sustained release dosage forms has become easier than ever before. This unit is perfectly suited for simulating the pH changes within the human body. By placing different media in each row, the device reflects varying in vivo gastrointestinal conditions of the body. An automatic sample transport between the rows allows the reliable testing of the extended or sustained release from different dosage forms in various pH zones. The simple to program RRT 10 is the perfect unit for multiple media pH changes for IV/IVC testing and dissolution profiling of a variety of release dosage forms (e.g. tablets, coated tablets and oblongs).

Vessels are placed inside an acrylic water bath with an outlet valve for easy cleaning and the automatic cover system of the RRT 10 reduces media evaporation.

Highlights



100% USP/EP/JP compliant



3 configurations available



Automated evaporation cover



Different tools available

Height of stroke

100 mm

20 mm

100 mm & 20 mm
(changable)

Vessel types

300 ml & 1000 ml
for reciprocating cylinder

50 m, 100 ml, 300 ml & 1000 ml
for different types of tools

50 ml, 100 ml, 300 ml & 1000 ml
for different types of tools







| Art. No. | RRT 10 BioDis |
|----------|---|
| 18532 | BioDis dissolution tester RRT 10 USP method 3 with 8 rows |
| 18533 | BioDis dissolution tester RRT 10 USP method 7 with 8 rows |
| 18534 | BioDis dissolution tester RRT 10 USP method 3 & 7 user changeable, 8 rows |

The highlights of the

USP 4 Flow-Through Cell DFZ II

The ERWEKA flow-through cell tester DFZ II can be used for various applications thanks to its wide range of available cell types, e.g. for testing poorly soluble products or low-dose formulations with sustained release.

Innovations as the cell design with increased leak-tightness and the optimized tubing system with quick locks allow a fast preparation and imple-

mentation of dissolution tests according to UPS method 4. The leaner cell bodies ensure an improved cell warming and can be heated individually. All USP 4 DFZ II systems can be easily controlled with the Disso.NET USP 4 dissolution software via a controller.



Standardized cell head

The new cell head fits all offered cell bodies and thus enables a faster assembly of cells while offering lower purchasing costs. Through a quick lock in the cell head faster tube mounting is also possible.

Excellent leak-tightness

Due to reducing the number of seals to 3 pieces per cell and using flat seals with an increased sealing surface, the process safety can be heightened.

Optimized cell bodies and individual cell heating

The reduction of the cell body provides a better heating and faster preparation of cells. Each cell can be heated individually via a rotary switch.

Highlights



100% USP/EP/JP compliant



Independent, closed flow-through system



Variety of different cells available



Controlled by Disso.NET USP 4



Compact & corrosion-resistant housing

The small footprint with clear arrangement of cells in one line saves laboratory space and offers a perfect visual control of the cells at all times. In addition, the tube organizer on the back of the device prevents mixing up the cell tubes.



Due to the 3-way-valve for water emptying on the back of the device, the water bath cleaning can be handled much easier. In addition, simple water temperature and water level control are possible with the water level pointer (colour coding) and the two openings for temperature sensors on the device cover.

ERWEKA



New improved

Cell design

Accompanying our flow-through systems, we offer a variety of different cells with a new improved design for different purposes - from the standard tablet cell to granulate & powder cells to cells for implants, suppositories and stents.

The new standardized cell head fits all offered cell bodies and facilitates along with the new standardized flat seals handling and assembly of the cells. The optimized cell bodies with decreased cell wall thickness guarantee an improved cell heating.

Thanks to this new cell concept, the cells can be mounted easier to the new flow-through tester DFZ II and thus enable a faster preparation and performance of dissolution tests.



New quick lock system on the cell head allows instant tube removing.



Special temperature calibration head.

Highlights



Variety of different cells available



Standardized cell head



Different cells for different purposes



Tablet cell 12 mm



Tablet cell 22.6 mn



Granulate &



Implant cell



Suppository cell



Stents cell



with one-way dialysis adapter



Tablet cell 22.6 mn with cream adapte



Tablet cell 22.6 mm with glass beads & tablet holder



Tablet cell 22.6 mm with glass beads & without tablet holder

The entry into USP 4 testing

USP 4 Stand-alone System



The ERWEKA stand-alone flow-through cell system is perfect for performing simple release tests with manual sampling. Therefore, the flow-through cell tester DFZ II offers with the ERWEKA piston pump HKP 720 and the ERWEKA heater an easy entry into testing with USP 4 systems for a small budget.

The valve-free piston pump transports the test medium with highest precision via seven channels to the flow-through cells and automatically adopts the setting of the flow rate. With the low-vibration heater the water in the water bath can be quickly heated to the required temperature.

| Art. No. | USP 4 Stand-Alone System |
|----------|---|
| 23437 | DFZ II Stand-Alone Flow-through-cell with HKP 720 |
| 23439 | DFZ II Stand-Alone Flow-through-cell with HKP + temperature sensors |
| 23440 | DFZ II Stand-Alone Flow-through-cell with IPC-8 |

Highlights



100% USP/EP/JP compliant



Flow-through cell with 7 test stations

ERWEKA



Simple release testing with manual sampling



USP 4 Dissolution Testen with automated analytic

USP 4 Closed Online System



The USP 4 Closed Online System is our solution with automated analytic for the USP 4 flow-through cell. The software controlled USP 4 system integrates USP 4 flow-through cell testing with directly connected analytic UV/Vis online measurement, resulting in an automated USP 4 workflow.

Furthermore, all features of the stand-alone system can be applied to our online system: the valve-free piston pump with highest precision and the low-vibration heater steadily holds the requested temperature of the waterbath. And our new and improved DFZ II USP 4 cells are also integrated into the software dialogs, making the use of the system as easy as possible.

| Art. No. | USP 4 Closed Online System |
|----------|--|
| 27032 | UV-Vis Online System DFZ II, HKP720, IPC 8, Shimadzu 1900, Controller+Disso.NET |
| 27033 | UV-Vis Online System,HKP720,DFZ II -Temp.,IPC8, Shimadzu1900,Controller,Disso.NET |
| Art. No. | USP 4 Closed On-/Offline System |
| 27004 | Closed On/Offline System, DFZ II, PT 100, Shimadzu 1900, HKP, FRL, PC, Disso.N |

Highlights



100% USP/EP/JP conform



Flow-through cell with 7 test stations



Software controlled by Disso.NET



Integrated UV-Vis analytic



Audit Trail

USP 4 Open Offline System



Features of the automated USP 4 Open Offline System

- Handling of unlimited media for testing of low soluble drug substances
- Fully USP compliant
- Automated sample collection
- Sampling of complete fractions into glass vials
- Sampling of representative fractions by splitting into waste and glas vials

| Art. No. | USP 4 DFZ II Open Offline System |
|----------|---|
| 27038 | Open Offline System, DFZ II with HKP 720, FRL 754, Workstation, Disso.NET USP 4 |
| 27039 | Open Offline System,DFZ II,Temp.Sensor, HKP 720, FRL 754, Workstation, Disso.NET |
| 27037 | Open Offline System, DFZ II, IPC-8, FRL 754, Workstation, Disso.NET |
| 18590 | Manual switching valve for pH change USP 4 |
| 18591 | Electronic switching valves 4x for pH change for up to 4 media |

USP 4 Closed Offline System







| Art. No. | USP 4 DFZ II Closed Offline System |
|----------|---|
| 27040 | Closed Offline System DFZ II, HKP 720,IPC-8, FRL 754, Workstation, Disso.NET |
| 27041 | Closed Offline System DFZ II, temp.sensor, HKP 720, IPC-8, FRL 754, Workstation |
| 17923 | LMT 2 Closed Loop unit for USP 4 incl. 500 ml bottles (7 pcs) |
| 19897 | 100 ml glass bottle (7 pcs.) with safety cap for LMT 2 |
| 19898 | 250 ml glass bottle (7 pcs.) with safety cap for LMT 2 |
| 20376 | 1000 ml glass bottle (7 pcs.) for LMT 2 |
| 18602 | Filter for USP 4, 0.7µm, 25 pcs, 25 mm |
| 18603 | Filter for USP 4, 1.4µm, 25 pcs, 25 mm |

Features of the USP 4 Closed Offline System

- Specific amount of min. 2 ml to max. 32 ml of media is pumped through the cell continually
- Media transfer station LMT 2 with 8x 1000 m vessels
- Fully USP compliant
- Fraction collection with 3-way valves
- Long duration test runs with optimized media evaporation
- Media replacement possible

USP 4 Open Offline System



Features of the automated USP 4 Open Offline System

- Handling of unlimited media for testing of low soluble drug substances
- Fully USP compliant
- Automated sample collection
- Sampling of complete fractions into glass vials
- Sampling of representative fractions by splitting into waste and glas vials

| Art. No. | USP 4 DFZ II Open Offline System |
|----------|---|
| 27038 | Open Offline System, DFZ II with HKP 720, FRL 754, Workstation, Disso.NET USP 4 |
| 27039 | Open Offline System,DFZ II,Temp.Sensor, HKP 720, FRL 754, Workstation, Disso.NET |
| 27037 | Open Offline System, DFZ II, IPC-8, FRL 754, Workstation, Disso.NET |
| 18590 | Manual switching valve for pH change USP 4 |
| 18591 | Electronic switching valves 4x for pH change for up to 4 media |





Easy media transfer with the

LMT₂

With the compact ERWEKA media transfer station LMT 2 a closed loop for performing long-term dissolution tests according to USP 4 can be easily created. The LMT 2 is therefore used as a medium reservoir and ensures an optimal media mixing and distribution through the whole release test.

The optimized tubing system with a new tube holder and rotatable bottle caps (safety caps) makes handling easier and saves valuable laboratory space. Using standardized laboratory glass bottles as media vessels also enables an easier media transport for saving and further analysis. The glass bottles are available in 500 ml as standard size and optionally in the sizes 100 ml, 250 ml and 1000 ml. With the comfortable keypad the stirring speed can be easily set.

Highlights



100% USP/EP/JP compliant



Wide range of vessel sizes



Improved tubing



Optimal media distribution

Full dissolution software solution for Flow-Through Cell

Disso.NET USP 4*

The ERWEKA Disso.NET USP 4 Software is the perfect companion for our USP 4 systems. The software takes over full control of our USP 4 systems and offers support for all USP/EP dissolution cells used in these systems. It also supports cells for special applications (e.g. cell with cream adapter) and visual guides for formulation placing in the respective cells

Disso.NET helps you with standard USP 4 dissolution jobs, handles qualifying tasks and provides control over each single function of the connected devices (e.g. pump, flow-through cell and sample collector). In addition, the software includes an easy to handle method editor for comfortable programming of dissolution methods (for highest safety in GMP environment). Our audit trail also generates detailed protocols of all events and times and thus enables tracing changes at any time.

Highlights



Audit Trail





Easy control of the USP 4 systems with Disso.NET



MS SQL Database

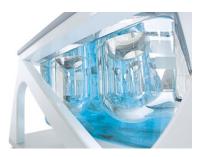


Advanced report generation

Dissolution Tester

General Options

Art. No. **General Options** 18331 2000 ml version, additional price for DT 72x/82x 18334 Evaporation cover for DT HH 21795 Evaporation cover with anti-rotation device for DT HH with ASS- 8 /14 18335 LED light strip for DT Vessel Illumination, needed for 24/7 video recording 18336 Automated tablet drop magazine for DT 72x/82x 18337 Automated tablet drop magazine for DT 141x/161x22342 Water stabiliser with colour indicator for DT, 100 ml blue



Water stabilizer 100 ml, blue



Evaporation cover for DT HH



Evaporation cover with anti-rotation device for DT HH with ASS-8/14 sampling station

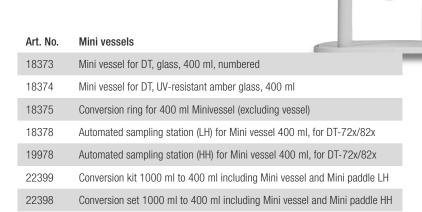
| Art. No. | CoC (Certificate of Compliance) |
|----------|--|
| 18395 | CoC for basket, per basket |
| 20267 | CoC for basket holders for LH / HH, per holder |
| 18414 | CoC for paddle over Disk, per Disk |
| 20268 | CoC paddle, per paddle |
| 20269 | CoC for shaft LH / HH, per shaft |
| 22444 | CoC for bundle, paddle, basket holder |
| 18369 | CoC for vessels, per vessel |
| 20272 | CoC for mini vessel, per vessel |
| 22449 | CoC for rotating cylinder, per rotating cylinder |
| | |

Vessels and Mini Vessels

| Art. No. | Vessels |
|----------|--|
| 18365 | Vessel for DT, glass, 1000 ml, numbered |
| 18366 | Vessel for DT, UV-resistant amber glass, 1000 ml, numbered |
| 18367 | Vessel for DT, glass, 2000 ml, numbered |
| 18368 | Vessel for DT, UV-resistant amber glass, 2000 ml, numbered |
| 19115 | Vessel with peak for DT, glass, 1000 ml |

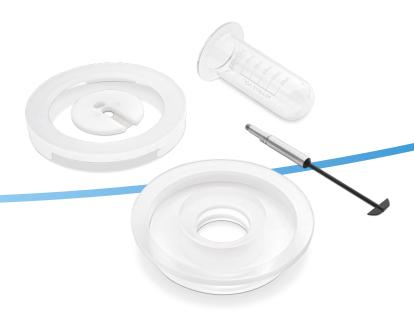


Glass vessel and UV-resistant vessel





The 400 ml Mini vessel apparatus is a reduced scale of the USP method 2, commonly used for low-dose formulations and poorly available drugs.



Dissolution Accessories

| Art. No. | DT Shafts for USP Methods 1, 2, 5, 6 |
|----------|---|
| 22391 | Shaft unit LH for basket or paddle (st. steel) or Bundle (st. steel), incl. carrier, numbered |
| 22436 | Shaft unit LH for paddle (PTFE coated), numbered |
| 22438 | Shaft set (2) LH for bundle basket holder + PTFE coated paddle, numbered |
| 22393 | Shaft LH 2000 ml for basket, paddle (st. steel) or bundle (st. steel) |
| 22394 | Shaft unit HH for Basket or Paddle (st. steel) or Bundle (st. steel), numbered |
| 22437 | Shaft unit HH for PTFE coated Paddle, numbered |
| 22439 | Shaft set (2) HH for Bundle basket holder + PTFE coated paddle, numbered |
| 22396 | Shaft HH 2000 ml for basket, paddle (st. steel), or bundle (st. steel) |
| | Shaft high head for |

Shaft high-head for PTFE paddle & basket



| Art. No. | Baskets | IISP 1 |
|----------|---------|--------|
| AIL NO. | Daontio | USF |

| 22402 | Basket holder, stainless steel, numbered |
|-------|--|
| 18391 | Basket, mesh 10, stainless steel, numbered |
| 18392 | Basket, mesh 20, stainless steel, numbered |
| 18393 | Basket, mesh 40, stainless steel, numbered |
| 18394 | Suppository basket, plastic |







Baskets mesh 10, 20 and 40 (standard)

| Art. No. | Paddles USP 2 | |
|----------|--|--|
| 22403 | Paddle, stainless steel, numbered | |
| 22404 | Paddle (PTFE coated) for 1000 ml, numbered | |
| 22405 | Paddle (PTFE coated) for 2000 ml, numbered | |
| 22406 | Bundle, paddle and basketholder, stainless steel, numbered | |
| 22407 | Bundle, paddle (PTFE coated), and basket holder, stainless steel, numbered | |
| | | |



Paddle, stainless steel, numbered



| Art. No. | Paddle over Disk USP 5 |
|----------|---|
| 18412 | Height Adjustment tool Paddle over Disk USP 5 Distance |
| 18413 | Paddle over Disk USP 5, incl. sieve mesh 125 μm , numbered |
| 21443 | Paddle over Disk USP 5, HH, 9/16 inch diameter sieve |



Paddle over Disk USP 5, for holding transdermal patch, mesh 125 µm, numbered





| Art. No. | Extraction Cell |
|----------|--|
| 18421 | Extraction cell, ID=20/27 mm, acc. to EP 2.9.4 |
| 22252 | Extraction cell, ID=32/38 mm, acc. to EP 2.9.4 |
| 22253 | Extraction cell, ID=40/45 mm, acc. to EP 2.9.4 |
| 22254 | Extraction cell, ID=50/52 mm, acc. to EP 2.9.4 |

| Art. No. | Felodipine basket |
|----------|--|
| 18422 | Felodipine stationary basket for low-head use |
| 18423 | V-shaped low head vessel cover (plastics) for fixing Felodipine basket |
| 18424 | V-shaped vessel cover (PTFE coated) for fixing Felodipine basket |
| 18425 | Felodipine stationary basket for high-head use |
| 18426 | Low-evaporation high-head vessel cover (plastics) for fixing Felodipine basket |
| 22411 | ERWEKA Wood Apparatus (intrinsic) for 1 test station |
| 18429 | Manual hydraulic press for Wood Apparatus |



Art. No. Sinkers

| 18379 | Japanese sinkers, set of 6 pcs, stainless steel, USP compliant |
|-------|--|
| 18380 | Spider sinkers, plastic, set of 6 pcs |





Spider sinkers, plastic, set of 6

| Art. No. | Enhancer Cell |
|----------|--|
| 22400 | Enhancer cell set, incl. 200 ml vessel round bottom and mini paddle HH shaft |
| 22401 | Enhancer cell set incl. 200 ml flat bottomed glass, mini paddle, HH shaft |
| 18382 | Vessel for Enhancer cell, 200 ml, glass, rounded bottom |
| 18384 | Enhancer cell (fluoropolymer) for testing creams, ointments, gels |
| 21612 | Vessel for Enhancer cell, 200 ml, glass, flat bottom |



Consumables

| Art. No. | Inline Filters |
|----------|--|
| 18430 | Filters (1.000 pcs), Poroplast, 1 µm |
| 18431 | Filters (1.000 pcs), Poroplast, 4 µm |
| 18432 | Filters (1.000 pcs), Poroplast, 10 µm |
| 21702 | Filters (10.000 pcs), Poroplast, 10 μm |
| 18433 | Filters (1.000 pcs), Poroplast, 20 µm |

| Art. No. | PVT Reference Tablets |
|----------|-------------------------------------|
| 18441 | Prednisone tablets, 1 pack (30 pcs) |
| 18442 | Prednisone, 250 mg |



Different types of filters



Mechanical Calibraion

| Art. No. | Tools Mechanical Calibration |
|----------|--|
| 18437 | Dissolution tester qualification kit |
| 18438 | Dissolution tester validation kit according to FDA, certified |
| 18439 | Qualification kit (upgrade) according to Mechanical Calibration standards of FDA |
| 18440 | USP 5 Calibration Tool for height measurement, certified |

Documents

| Art. No. | QA Dokumente |
|----------|---|
| 26980 | IQ documents DT 126/128 Light / DT 62x, DT 72x, DT 82x |
| 26981 | OQ documents DT 16/128 Light, DT 62x, DT 72x, DT 82x |
| 26979 | IQ documents DT 1212 Light / DT 141x / 161x |
| 26982 | OQ documents for DT 1212 Light, DT 141x, DT 161x |
| 25150 | PVT Documents for all DT Dissolution Tester |
| 25850 | FIP (Final Inspection Protocol) for DT Dissolution Tester |





Manual Sampling

| Art. No. | Manual Sampling |
|----------|---|
| 18357 | Manual sampling cannula LH USP 1 (basket), stainless steel |
| 18355 | Manual sampling cannula LH USP 2 (paddle), stainless steel |
| 18361 | Manual sampling cannula HH USP 1 (basket), stainless steel |
| 20422 | Manual sampling cannula HH USP 2 (paddle), stainless steel |
| 20411 | Manual sampling cannula LH USP 1 (basket), stainless steel for 2000 ml vessel |
| 20425 | Manual sampling cannula LH USP 2 (paddle), stainless steel for 2000 ml vessel |
| 25077 | Syringe connected to stainless steel sampling probe LH |
| 25078 | Syringe connected to stainless steel sampling probe HH |

Manual sampling cannula, LH USP 1 with syringe connected to stainless steel sampling probe



Syringe connected to stainless steel sampling probe

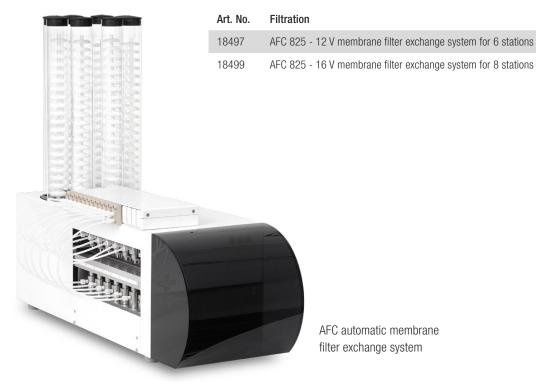
Automated Sampling

| Art. No. | Automated Sampling |
|----------|---|
| 18340 | DT i-Version motor upgrade for DT 82x/161x |
| 18346 | 8 pcs electronic temperature sensors for sampling station |
| 18350 | Cleaning reservoir (acrylic glass) for ASS-8 (DT 72x/82x) |
| 18352 | Cleaning- and calibrationreservoir for ASS-8 sampling station with Disso.NET |
| 18351 | Cleaning reservoir (acylic glass) for ASS-14 with DT 141x/161x |
| 23208 | Cleaning- and calibrationreservoir for ASS-14 sampling station with Disso.NET |



Automated sampling station ASS-8 or top of a DT from the DT 720 series

Dissolution System Options



AFC automatic membrane filter exchange system

Art. No. FRL sample collector racks

| 26990 | Rack 26 x 8 for 12 ml glass tubes |
|-------|---|
| 26991 | Rack 18 x 8 for 25ml glass tubes |
| 18509 | Rack for 26 x 8 HPLC vials, 1.8 ml |
| 18510 | Rack for 26 x 8 glass tubes, 4.0 ml |
| 18511 | Recalibration rack for HPLC vials 1.8 ml and 4.0 ml |



Rack with HPLC vials

Art. No. **Others**

23172 Metrohm pH Meter for connection to Disso.NET



Sampling into UV-Vis glass tubes

| Art. No. | Glass tubes for FRL |
|----------|---|
| 18512 | Glass tubes 12 ml for FRL, 100 pcs. |
| 18513 | Glass tubes 25 ml for FRL, 100 pcs. |
| 18514 | Glass tubes amber glass 25 ml, 100 pcs. |

| Art. No. | Cuvettes for UV/Vis |
|----------|---|
| 18521 | Cuvette, 10 mm path length, flow-through optimised (standard) |
| 18518 | Cuvette, 1 mm path length |
| 18520 | Cuvette, 5 mm path length |

| Art. No. | QA Documents |
|----------|---|
| 18529 | IQ/OQ documents Offline System for first installation |
| 20952 | OQ documents Offline System |
| 18530 | IQ/OQ documents Online System |
| 20953 | OQ documents Online System |
| 18531 | IQ/OQ documents On-/Offline System UV-Vis |
| 20954 | OQ documents On-/Offline System UV-Vis |
| 18494 | IQ/OQ documents On-/Offline System HPLC |
| 20957 | OQ dokuments On-/Offline System HPLC |
| 24958 | AVT documents for Offline, Online, On-/Offline, RoboDis Systems |
| 26374 | SOP AVT Automation Verification Test Diss. Systems |
| 25860 | FAT Protocol Dissolution Systems |
| 26870 | System inspection protocol SIP for DT System with Disso.NET |
| 26871 | Final inspection protocol for Offline system |



Contact

Are you curious and want to find out more? Head over to our website and download our product brochures, watch videos of our equipment in action or find the ERWEKA dealer of your country.



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