Dissolution **Guide** 2016

ERWEKA

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-only testing with the DT 126/8 light up to the high-volume tester DT 161x.

Dissolution System

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

Fully automated Dissolution System RoboDis II

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

Disso.NET Software

Our advanced dissolution software solution Disso.NET is able to control all our dissolution systems.

Pumps

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

Dissolution Options

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

Media Preparation

Dissolution tests require prepared media - we offer the perfect companion to your dissolution tester for fast media preparation and filling of vessels.

USP method 3/7

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

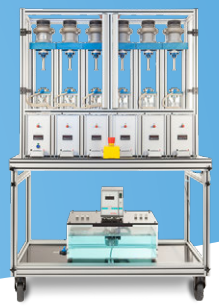
USP 4

USP method 4 is supported by our Flow-Through-Cell DFZ 720, available as stand-alone or as a system.

Chewing Gum Tester DRT

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

WORLD EXCLUSIVE!



Overview

USP Methods

USP Method 1 - Basket

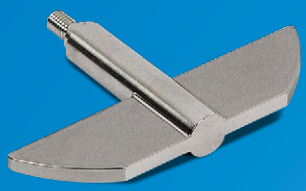
Application

- Immediate / Extended and delayed release forms
- 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: Fluid Movement

Advantages

- Easy pH change
- Hydrodynamic can 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: Fluid Movement

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

Application

- Transdermal patches
- Floating drugs
- Unguents
- Emulsions
- Agitation method: Rotating Stirrer

Advantages

- Standard equipment (USP 2 - paddle)

USP Method 6 - Rotating Cylinder

Application

- Transdermal patch
- Agitation method: Rotating Stirrer

Advantages

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

USP Method 7 - Reciprocating Holder

Application

- Transdermal patches
- Extended release dosage forms
- pH profiles
- Agitation method: Reciprocation

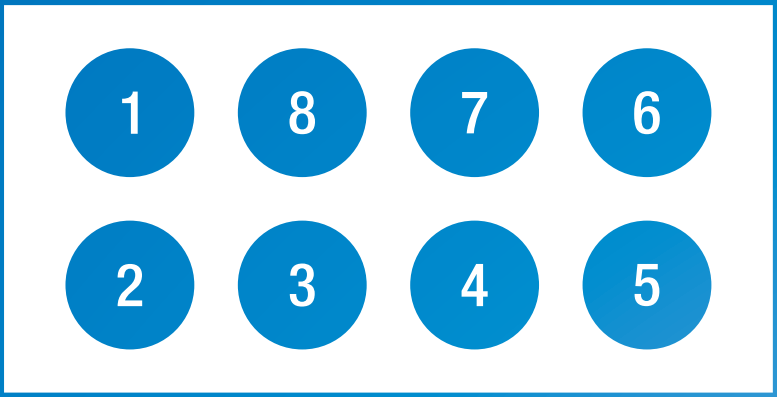
Advantages

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

Different holder types:

- Acrylic Rod: Extended release tablets
- Angled Disk: Transdermal system
- Fluoropolymer cylinder: Transdermal system
- Spring holder: Extended release tablets
- Reciprocating holder: Transdermal system

Numbered Test Stations



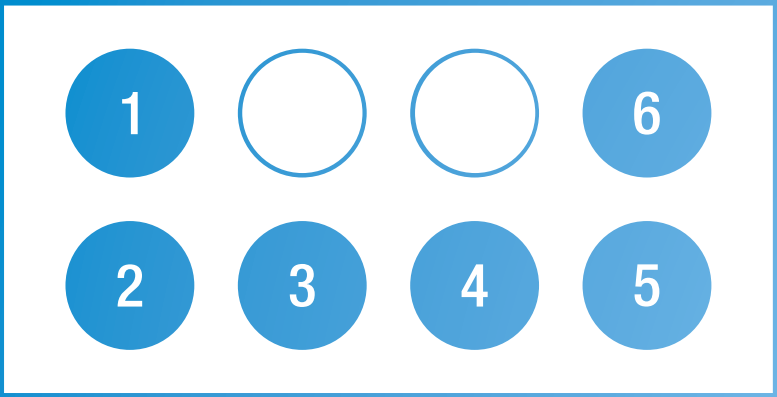
Schematic view of ERWEKA test stations

ERWEKA's dissolution tester can be equipped with 6 to 8 (12 to 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 Tester of the DT 720 and 820 series always come with inlets for 8 vessels, which are covered with blinds if a DT with 6 or 7 stations is ordered.

Important: Dissolution Testers with less then 8 stations can be upgraded by ERWEKA service.



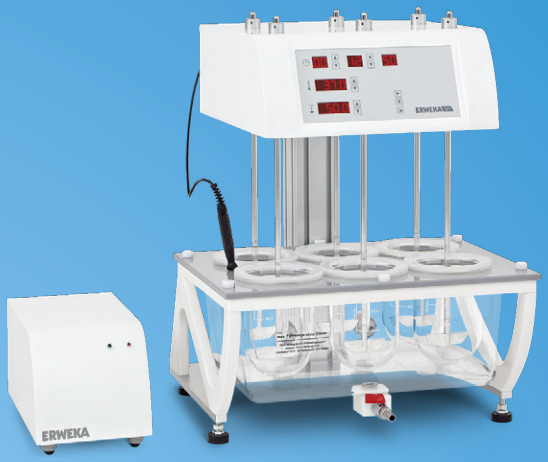
Vessel configuration example DT 726 or DT 826

Low-head, high-head and cleaning position

ERWEKA's dissolution testers 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 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. 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.

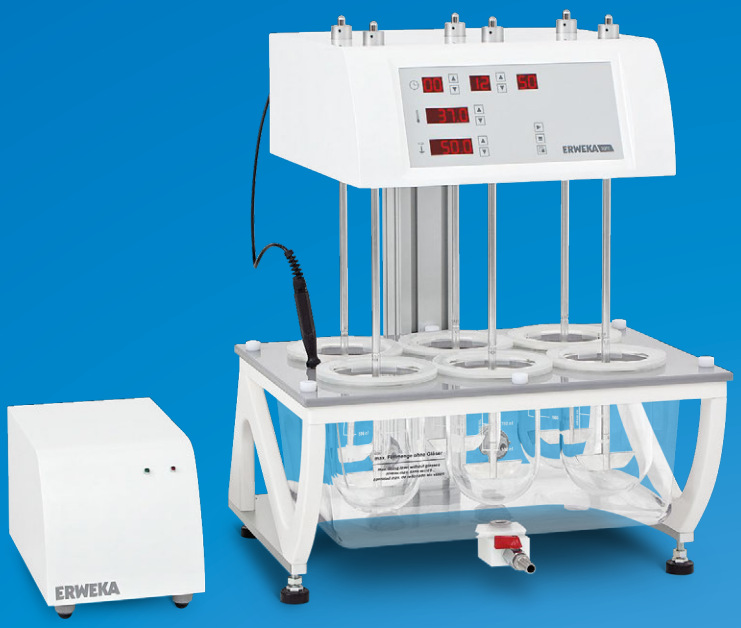
Cleaning position

The cleaning position is the up-most position of the dissolution testers' head. It makes cleaning effortless and easy.

Dissolution Tester

DT 126/8 light

The new ERWEKA light series delivers the proven ERWEKA quality in a comprehensive economic package for a budget for simple dissolution testing with USP method 2 (paddle) and low volume.



Best used for

- USP method 2 and optionally USP method 1
- Manual testing

Art. No.	Dissolution Tester DT 126/8 light
19996	DT 126 light Dissolution Tester with 6 test stations
20412	DT 128 light Dissolution Tester with 8 test stations

Dissolution Tester

DT 720 Series

ERWEKA DT 720 series has been designed in accordance with USP/EP/JP requirements for testing tablets and other dosage forms.

It combines state-of-the-art with excellent and user-friendly design. The high-head and low-head operating modes offer highest flexibility. The tester can be used as a stand-alone device as well as a dissolution system equipped with an automated sampling station and operated via the ERWEKA Disso.NET software.

Best used for

- USP methods 1, 2, 5 and 6
- Online System with UV-Vis or HPLC

Art. No.	Dissolution Tester DT 720 Series
18316	DT 726/1000 LH/HH Dissolution Tester with 6 test stations
18317	DT 727/1000 LH/HH Dissolution Tester with 7 test stations
18318	DT 728/1000 LH/HH Dissolution Tester with 8 test stations

Dissolution Tester

DT 820 Series

Highlights

- 100% USP/EP/JP compliant
- High-head and low-head mode
- USP methods 1, 2, 5 and 6
- Easy cleaning

Best used for

- Direct control of offline system possible

Overview

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

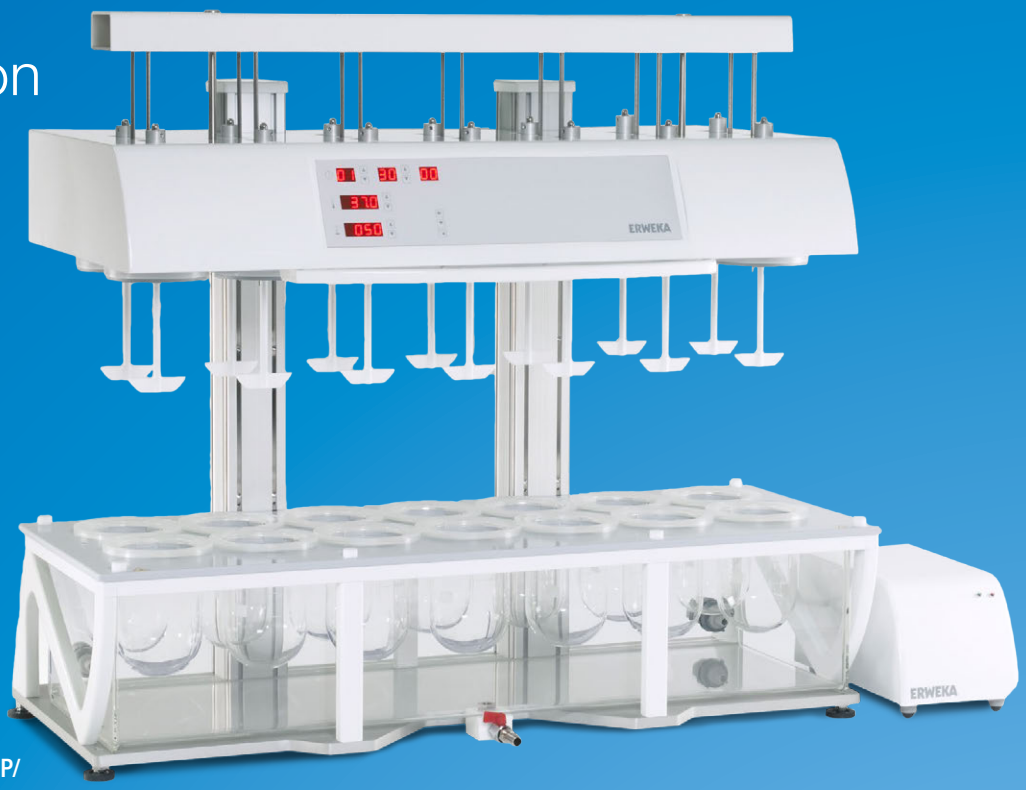
The DT 820 series can be equipped with 6, 7 or 8 test stations and be used in high-head or low-evaporation mode. It offers an OQ traffic light to show USP/EP/JP compliance, a low evaporation cover as well as an external temperature sensor for checking the water bath.

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.

Art. No.	Dissolution Tester DT 820 Series
18324	DT 826/1000 LH/HH Dissolution Tester with 6 test stations
18325	DT 827/1000 LH/HH Dissolution Tester with 6 test stations
18326	DT 828/1000 LH/HH Dissolution Tester with 6 test stations

Dissolution Tester

DT 141x



Highlights

- 100% USP/EP/JP compliant
- Test 12/13/14 tablets or 2 batches with 6 or 7
- USP methods 1, 2, 5 and 6
- Easy cleaning
- Manual & semi-automated

Best used for

- High volume Online System with UV-Vis or HPLC

Overview

The DT 1410 series is based on the proven DT 720 series and can be configured for 12, 13 or 14 test stations arranged in two rows.

The DT 141x provides the possibility of performing one test with 12, 13 or 14 tablets or two tests with 6 resp. 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, 2000 ml) and is available with high-head (maximum access) and low-head (low-evaporation version; for automation) mode depending on customer specifications.

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 141x
18319	DT 1412 (LH/HH) 1000 ml Dissolution Tester with 12 test stations
18320	DT 1413 (LH/HH) 1000 ml Dissolution Tester with 13 test stations
18321	DT 1414 (LH/HH) 1000 ml Dissolution Tester with 14 test stations

Dissolution Tester

DT 161x

Overview

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

The DT 1610 series can be equipped with 12, 13 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.

Highlights

- 100% USP/EP/JP compliant
- Test 12/13/14 tablets or 2 batches with 6 or 7
- USP methods 1, 2, 5 and 6
- Easy cleaning

Best used for

- Direct control of high volume offline system

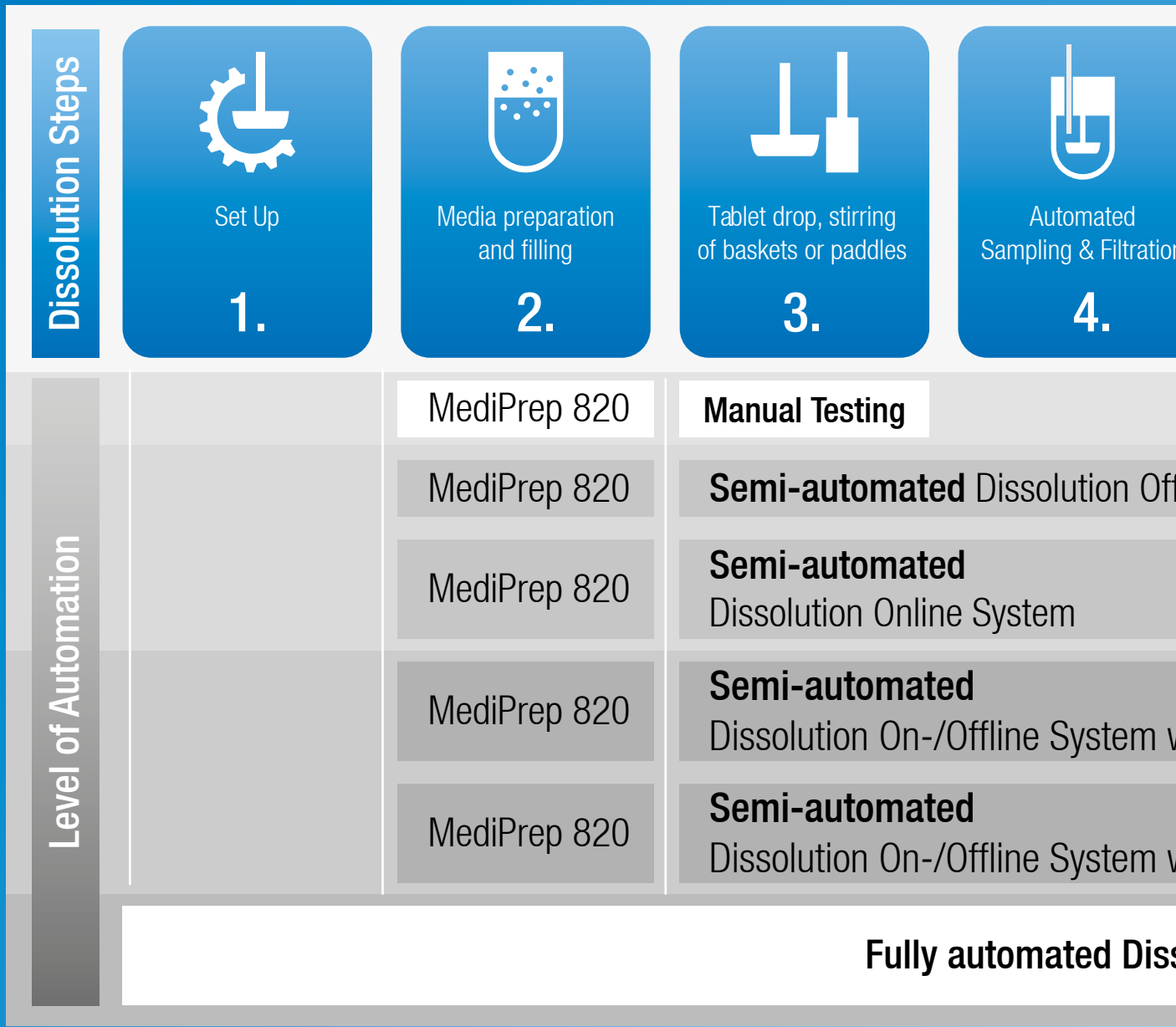
Art. No.	Dissolution Tester DT 161x
18328	DT 1612 (LH/HH) 1000 ml Dissolution Tester with 12 test stations
18329	DT 1613 (LH/HH) 1000 ml Dissolution Tester with 13 test stations
18330	DT 1614 (LH/HH) 1000 ml Dissolution Tester with 14 test stations

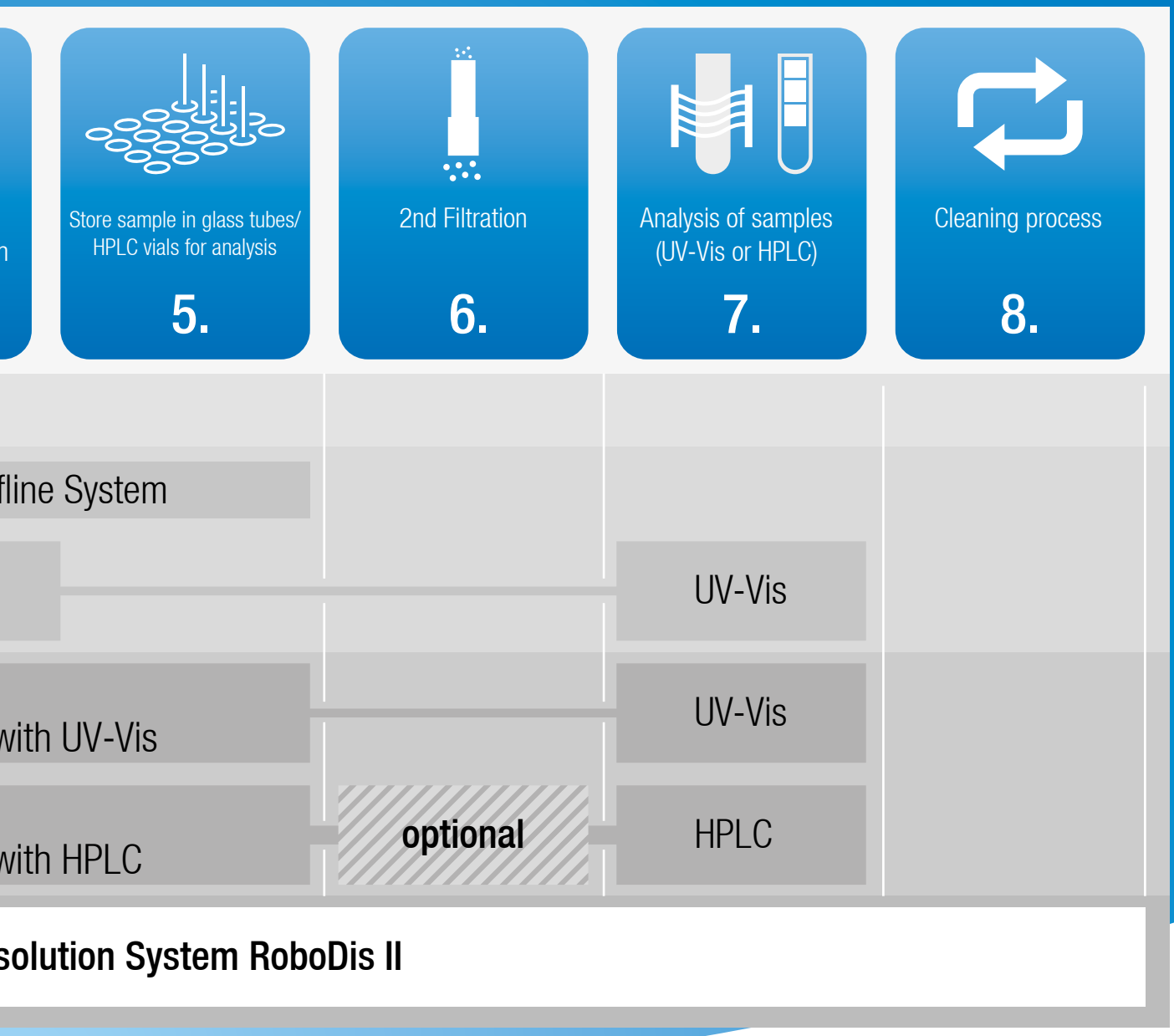
DT 1614 with ASS-14 automated sampling station

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 (four, with MediPrep 820) 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 analytic automates five steps of the dissolution process (six, with MediPrep 820).

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




Store sample in glass tubes/ HPLC vials for analysis
5.
2nd Filtration
6.
Analysis of samples (UV-Vis or HPLC)
7.
Cleaning process
8.
fline System
UV-Vis
with UV-Vis
UV-Vis
optional
with HPLC
HPLC
solution System RoboDis II

ERWEKA

Dissolution Offline System

Highlights

- 100% USP/EP/JP compliant
- Direct control of the complete system by DT 820
- USP methods 1, 2, 5 and 6
- Sample collector FRL 624 / 724 / 824

Overview

The ERWEKA Dissolution Offline Systems are controlled by a DT 820 series dissolution tester. The DT 820 series offers advanced intelligence and features for stand-alone operation or the control of a complete dissolution offline sampling system. It allows storage of up to 60 product test-run parameters, that can be recalled for future tests.

The DT 820 series equipped with iVersion comes with integrated intelligence for controlling 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 FRL x24 for storing the samples into 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.

Art. No.	Dissolution Offline System
18445	Standard Offline Dissolution System with IPC 8 for DT 826
18446	Standard Offline Dissolution System with IPC 8 for DT 827
18447	Standard Offline Dissolution System with IPC 8 for DT 828
18448	Standard Offline Dissolution System with IPC 16 for DT 1612
18449	Standard Offline Dissolution System with IPC 16 for DT 1614

ERWEKA Systems

Dissolution Online System UV-Vis

Overview

The ERWEKA Dissolution Online Systems are the perfect, semi-automatic solutions for dissolution testing with automated UV-Vis online analysis.

The DT 720 series with the integrated, automated ASS-8 sampling station transports freshly sampled media directly to the UV-Vis analysis device (several brands available). There, the samples can be measured and the results can then be stored within our advanced Disso.NET dissolution software, which controls the Online System.

Our Disso.NET software can control different UV-Vis spectrophotometers like Shimadzu UV-1800, Analytica Jena Specord 210/8 and 210/16 or the Agilent Cary 8454. These photometers are fully integrated in our systems.

Art. No.	Dissolution Online System UV/Vis
18464	UV/VIS Online System with Shimadzu 1800, IPC 8 for DT 72x + Disso.NET
20632	UV-VIS Online System with Analytic Jena Specord 210/8, IPC 8, Disso.NET
18465	UV-VIS Online Dissolution System Agilent 8454 with IPC 8 for DT 72x + Disso.NET
18472	UV-VIS Online System with Analytic Jena Specord 210/16 IPC for DT 141x

Highlights

- 100% USP/EP/JP compliant
- Controlled by Disso.NET
- USP methods 1, 2, 5 and 6
- Advanced UV-Vis analysis

ERWEKA Systems

Dissolution On-/Offline System UV-Vis

Highlights

- 100% USP/EP/JP compliant
- Controlled by Disso.NET
- USP methods 1, 2, 5 and 6
- Advanced UV-Vis analysis
- Sample collector and storage

Overview

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.

After analysis has been completed, the samples are comfortably stored by our very own sample collector FRL 624/724/824 for later HPLC analysis or as reference standard.

Art. No.	Dissolution On-/Offline System UV-VIS
18475	UV-VIS On-/Offline Dissolution System Shimadzu 6 channel for DT 72x
18476	UV-VIS On-/Offline Dissolution System Agilent 8454 6-channel for DT 726
18478	UV-VIS On/-Offline Dissolution System Analytic Jena Specord 210/16 for DT 141x

ERWEKA Systems

Dissolution On-/Offline System HPLC

Overview

The ERWEKA HPLC On-/Offline Dissolution System, 100 % compliant with all harmonized pharmacopoeias, is the perfect semi-automated solution for HPLC online analytic and features a high degree of automation and flexibility. It combines ERWEKA's high quality dissolution tester (DT 720 series) with CTC sampling and online HPLC chromatography. The system is controlled by the fully validated ERWEKA Disso.NET software and offers a high efficient sample management.

In addition, the HPLC On-/Offline Dissolution System uses an innovative flow-through system of sealed PEEK-vials. For pumping the test media from the dissolution tester to the CTC sampler two solutions can be implemented: a peristaltic pump or an ERWEKA piston pump. In case of filtration from 1 µm porosity, test samples can be withdrawn from the vessels through poroplast filters using a peristaltic pump. If a filtration from 0.45 µm porosity is required, the membrane filter changer AFC 825 or a double filtration station in combination with a high-precision ERWEKA piston pump PVP can be used instead. Connecting the system to the Disso.NET software provides not only easy und precise system operation, but also significantly facilitates the test process through the automatic recording of sampling times, temperature and rotation speed in each vessel (= documentation of all system actions).

Advanced intelligence with excellent, user-friendly design as well as dissolution testing with highest efficiency are hence offered by the ERWEKA HPLC On-/Offline Dissolution System.

Art. No.	Dissolution On-/Offline System HPLC
18479	HPLC On-/Offline Dissolution System with IPC 8 peristaltic pump
18480	HPLC On-/Offline Dissolution System with PVP 620 piston pump

Highlights

- 100% USP/EP/JP compliant
- Controlled by Disso.NET
- USP methods 1, 2, 5 and 6
- CTC sample collector and storage for HPLC
- Online HPLC chromatography

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, granules or powders - 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 filter down to 22 µm and even double filtration are supported.

pH half change and pH full change (USP methods A & B)

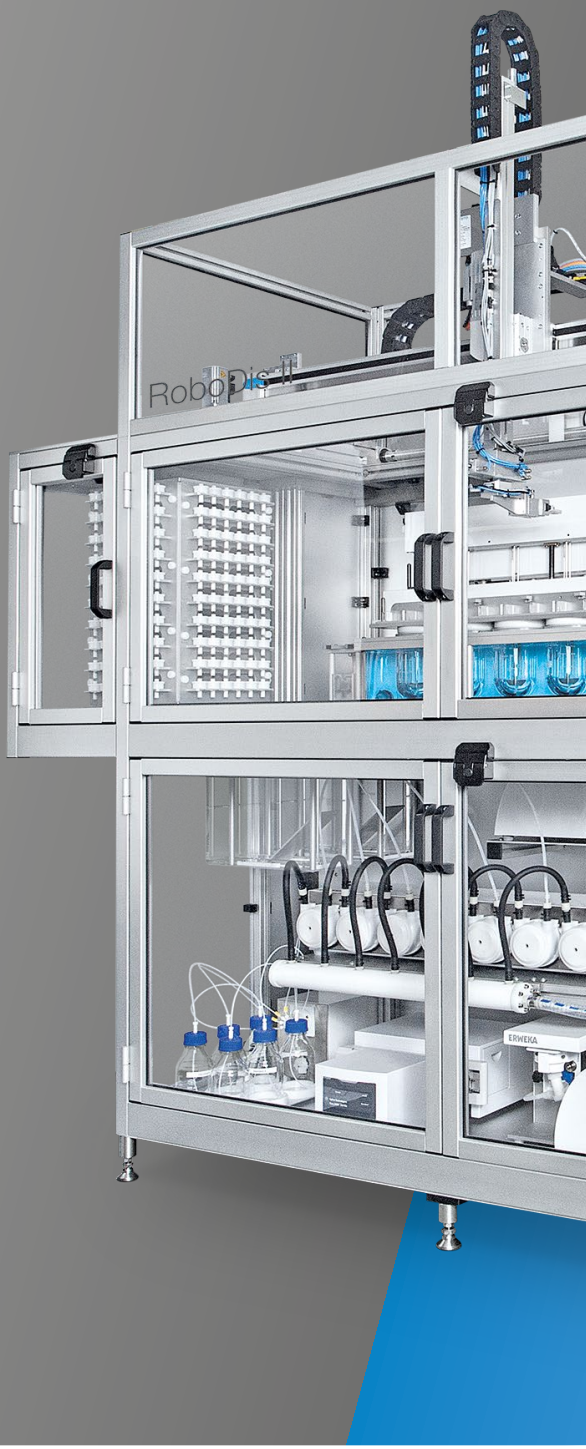
The fully automated ph change (both half and full possible) are supported by the RoboDis II. Just configure your method using the powerful Disso.NET software and run your test – the RoboDis II will automatically take care of the rest.

Broad range of analytics available

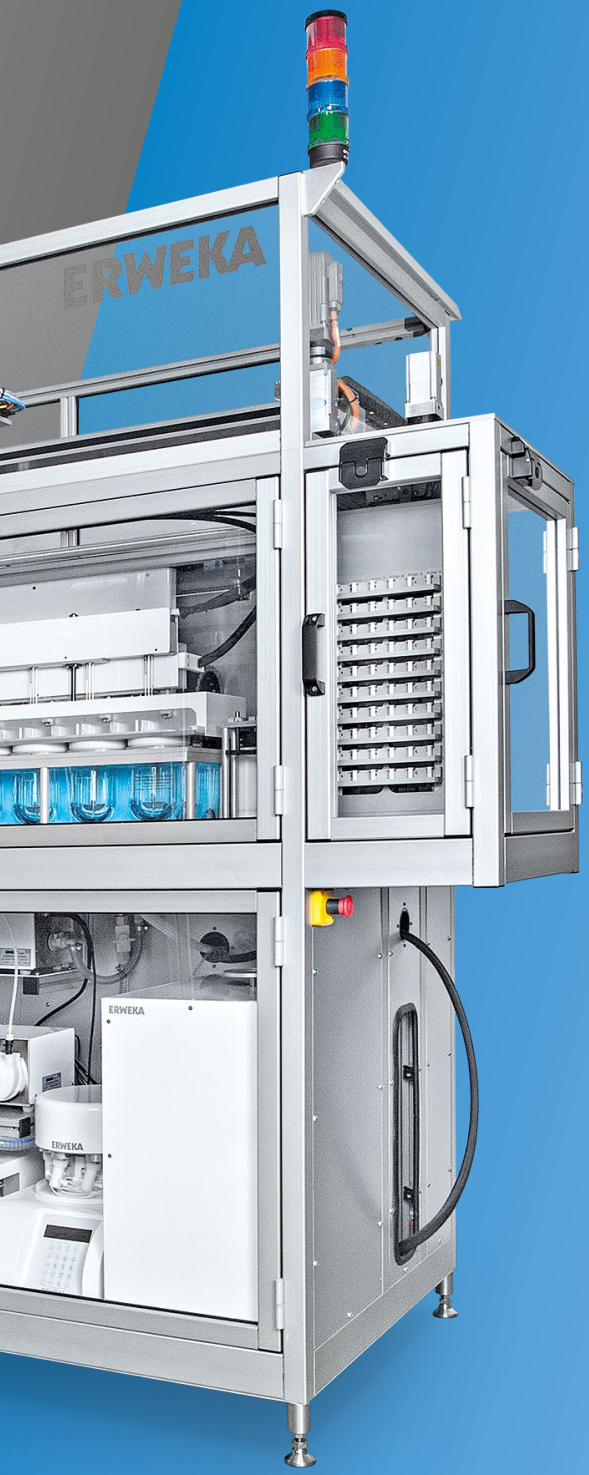
RoboDis II supports a broad range of analytical devices. Simple UV-Vis spectrophotography, sophisticated chromatography using HPLC or even a combination of both - the RoboDis II handles all of it.

6 reference standards

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



The Productivity Booster **for Quality Control**



Planned productivity with 10, 20 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, 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.

Parallel approach

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

Robotic precision & integrated error control

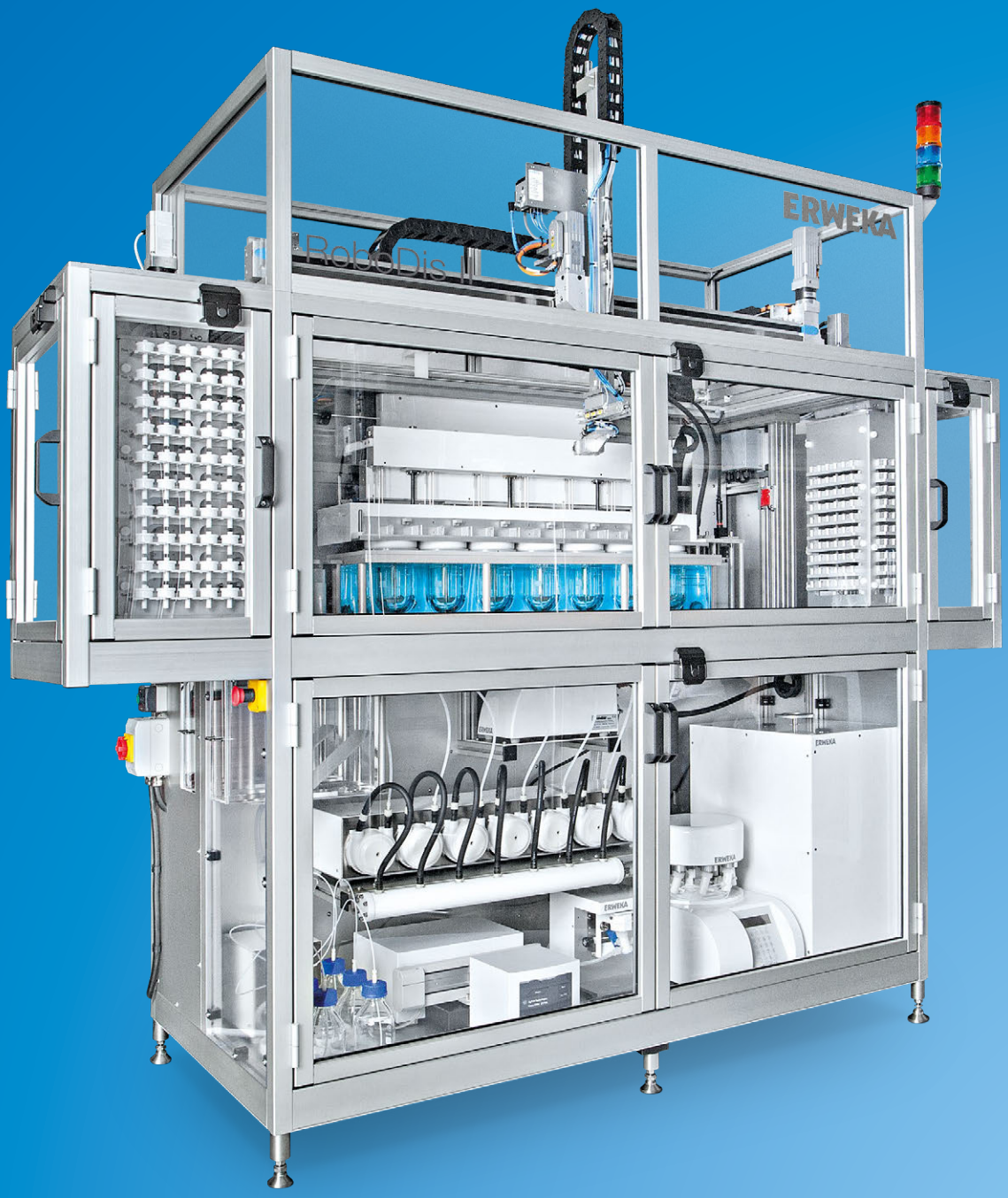
Every dissolution step is fully automated and is completely tracked by the system itself. This means, that every task that RoboDis II performs during a test is identically repeated in the next test, thus removing the human error factor completely. The system offers highest reliability and allows the 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 units and workers are needed to perform 10 batches per day. *Do the math!*

Fully automated Dissolution System

RoboDis II

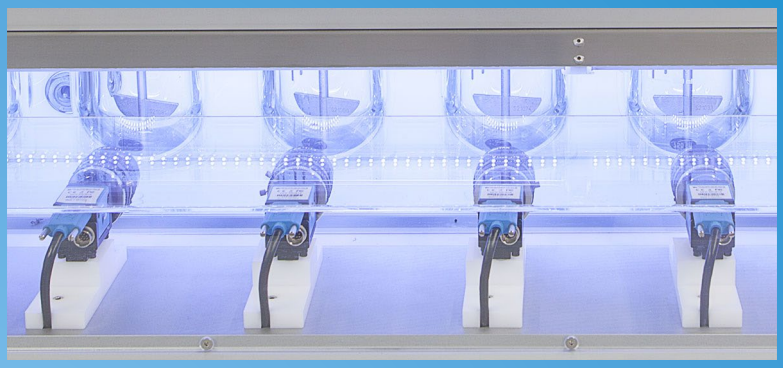


The Productivity Booster
RoboDis II

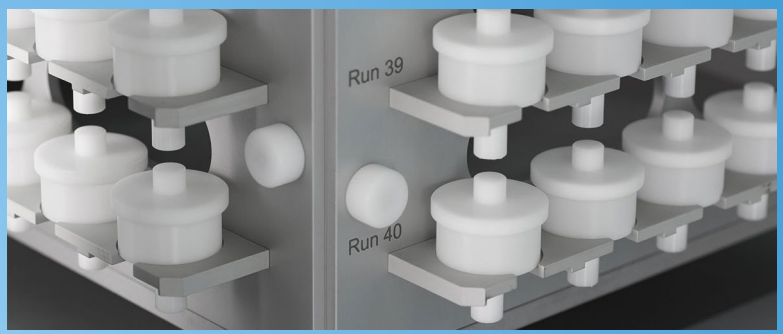
The fully automated dissolution system is already used in quality control and R&D by several multinational companies and has brought a huge increase in productivity. It fully automatically handles 10, 20 or 40 batches of dissolution testing USP method 1 basket or method 2 paddle in a parallel approach, 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, set-up of dissolution tester, testing, automated sampling, online analytics (UV-Vis or HPLC) and the whole cleaning process are performed 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 and light sensor checks, this system runs absolutely precise and reliable, minimizing human error. It is human error proofed so to say.



Real 24/7 testing with LED light bar and six ethernet cameras



New 40 batch solution for continuous testing 24/7

Highlights

- 10, 20 or 40 batches in one test run
- 100% USP/EP/JP compliant
- Controlled by Disso.NET
- USP methods 1 and 2
- Vacuum degassing
- pH half change (standard) or full change (optional)
- Closed online UV-Vis analysis
- HPLC analysis
- System Suitability Tests (SST)
- Video monitoring

Full dissolution software solution

Disso.NET

Highlights

- 100% — Full audit trail according to 21 CFR Part 11
- Disso.NET — For DTs of series 720, 820, 1410 and 1610
- Support for USP methods 1, 2, 4, 5 and 6
- MS SQL Database
- Advanced report generation

The ideal companion to our dissolution systems

The ERWEKA Disso.NET software is the perfect 21 CFR Part 11 compliant companion to our dissolution systems. The software offers support of all methods manageable with the ERWEKA DT dissolution systems as well as the automated RoboDis II and the DFZ 720 USP 4.

Disso.NET helps you with standard dissolution jobs, handles qualifying tasks and provides control over each single function and connected device (e.g. dissolution tester or UV-Vis spectrophotometer). Our audit trail generates a detailed protocol recording all events and times. The software includes an easy to handle method editor for highest repeatability. After finishing the dissolution test, Disso.NET creates reports with your corporate logo as PDF-file or exports your results (e.g. as XML-file).

Art. No.	Disso.NET
18673	Disso.NET dissolution software
18674	Upgrade Disso.NET dissolution software within version
18675	Upgrade Disso.win to ERWEKA Disso.NET

Overview

Pumps for Dissolution Systems

	Peristaltic pump	ERWEKA piston pump	ERWEKA Piston Pump
Pump	**IPC 8 / 16**	**PVP 620 / 720 / 820 /**	**PVP 1220 / 1420**
Channels	8 or 16	6, 7 or 8	12 or 14
Valves	-	-	-
Accuracy	+/- 0.5 ml	+/- 0.5 ml	+/- 0.5 ml
Dilution	-	-	-
Media replacement	Standard	Standard	Standard
Double filtration (option)	✓ (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, low maintenance even at high throughput, **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 fully automated dissolution systems**

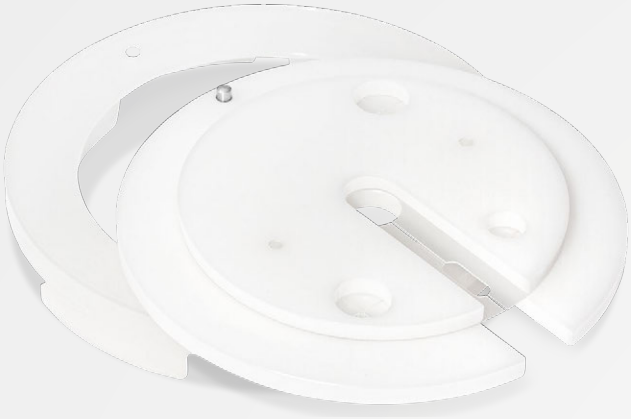
Dissolution Tester

General Options

Art. No.	General Options
18331	2000 ml version, additional price for DT 62x/72x/82x
18332	Print LAN converter for the data transfer to network printers
18333	External cooling device for DT with autonomous operation
18334	Evaporation cover for DT HH manual sampling
21795	Evaporation cover with anti-rotation device for DT HH with ASS- 8 /14
18335	Illumination of the DT water bath
18336	Automated tablet drop magazine for DT 72x/82x
18337	Automated tablet drop magazine for DT 141x/161x
18338	Video system USB 3.0 with 6 cameras for dissolution test monitoring
18339	Spare part kit for DT 6/7/82x
22342	Water stabiliser with colour indicator for DT, 100 ml blue

Water stabilizer 100 ml, blue

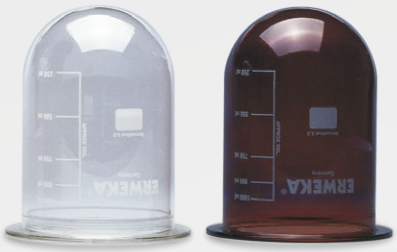
Evaporation cover for DT HH



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

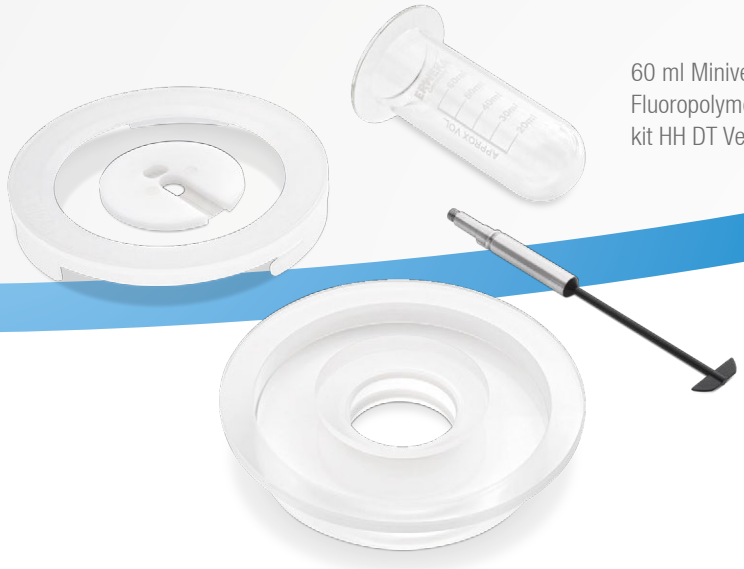
Vessels & Mini Vessels



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
18370	Rack for 8 vessels
18371	Rack for 8 paddles, baskets
18372	Rack for 16 paddles, baskets

60 ml, 100 ml and 400 ml vessels

Art. No.	Mini vessels
18373	Minivessel for DT, glass, 400 ml, numbered
18374	Minivessel for DT, UV-resistant amber glass, 400 ml
18375	Conversion kit for 400 ml Minivessel (excluding vessel)
18378	Automated sampling station (LH) for Minivessel 400 ml, for DT-72x/82x
19978	Automated sampling station (HH) for Minivessel 400 ml, for DT-72x/82x
20482	100 ml Minivessel, Minipaddle Fluoropolymer, incl. conversion kit HH DT vessel
20575	60 ml Minivessel, Minipaddle Fluoropolymer, incl. conversion kit HH DT
21598	60 ml Minivessel amber glass, MiniPaddle and Adaption for HH Dissolution Tester
22399	Conversion kit 1000 ml to 400 ml including Minivessel and Minipaddle LH
22398	Conversion set 1000 ml to 400 ml including Minivessel and Minipaddle HH



60 ml Minivessel, Minipaddle Fluoropolymer, incl. conversion kit HH DT Vessel

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
22394	Shaft unit HH for basket or paddle (st. steel) or Bundle (st. steel), incl. carrier, numbered
22437	Shaft unit HH for paddle (PTFE coated), numbered
22439	Shaft set (2) HH for Bundle basket holder + PTFE coated paddle, numbered

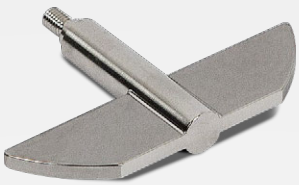
NEW: Basket holder, stainless steel, 2 O-rings, numbered

Art. No.	Baskets USP 1
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

Bundle, paddle (PTFE coated) & basket holder, stainless steel



Paddle, stainless steel, numbered

Art. No.	Paddle over Disk USP 5
18412	Paddle over Disk spacer to use standard paddle and shaft
18413	Paddle over Disk USP 5, for holding transdermal patch, mesh 125 µm, numbered
21443	Paddle over Disk, high and low head USP 5, 2 9/16 inch, numbered
21444	Paddle over Disk, high and low head USP 5, 3.5 inch, numbered

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

Rotating Cylinder

Art. No.	Rotating Cylinders USP 6
22408	Rotating cylinder, stainless steel, short, numbered
22409	Rotating cylinder, stainless steel, long, numbered

Art. No.	Enhancer Cell
22400	Enhancer cell set, incl. 200 ml vessel round bottom and mini paddle HH
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

Enhancer Cell

Plastic funnel

Art. No.	Funnel for granules
18381	Plastic funnel with extension for pouring granulates/powder

Spider sinkers, plastic, set of 6

Japanese Sinkers, set of 6

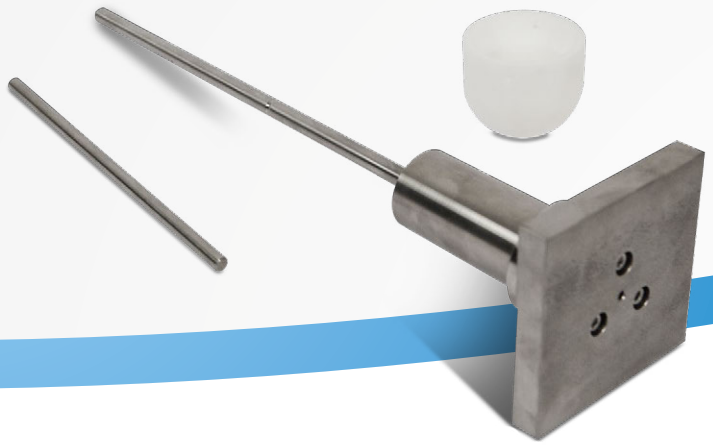
Art. No.	Sinkers
18379	Japanese Sinkers, set of 6 pcs, stainless steel, USP compliant
18380	Spider Sinkers, plastic, set of 6 pcs

Extraction Cell

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

Felodipine stationary basket

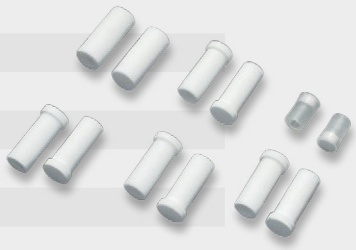
Art. No.	Felodipine basket
18422	Felodipine stationary basket for low-head use
18423	V-shaped low head vessel cover (plastics) for fixing Felodipine basket
18424	V-shaped vessel cover (PTFE coated) for fixing Felodipine basket
18425	Felodipine stationary basket for high-head use
18426	Low-evaporation 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



Wood Apparatus
for 1 test station

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
18434	Filter, stainless steel, 20 µm
18435	Filter, stainless steel, 50 µm
18436	Filter, stainless steel, 100 µm



Art. No.	Membrane Filters
18500	1 pack of filters (200 pcs), membrane 0.45 µm ROBY
18501	1 pack of filters (200 pcs), membrane 0.7 µm ROBY
18502	1 pack of filters (200 pcs), membrane 1 µm ROBY

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

Mechanical Calibration

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	Validation tool for height adjustment, certified

Art. No.	QA Documents
20477	IQ/OQ/PVT documents for DT 126/128 light
18443	IQ/OQ/PVT documents for DT 62x/72x/82x Series / Mechanical Calibration acc. FDA
18444	IQ/OQ/PV documents for DT 141x/161x Series, Mechanical Calibration according FDA

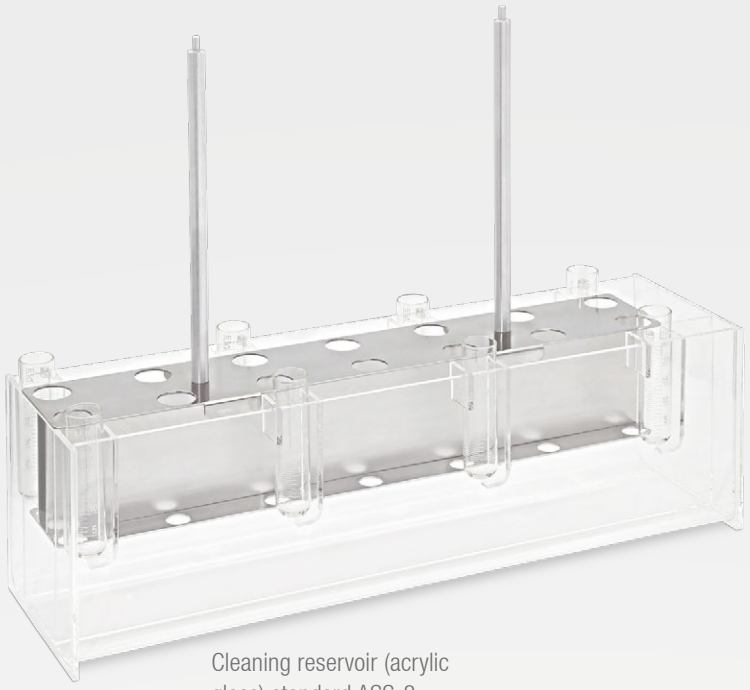
Sampling Manual

Art. No.	Sampling Manual
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
18363	Syringe connected to stainless steel sampling probe
18364	Eppendorf single handedly operating sampling pipette, LH DT
21329	Manual sampling cannula with refill tube for 60 ml vessel HH-USP 2 (Paddle)

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

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

Sampling Automated



Cleaning reservoir (acrylic glass) standard ASS-8

Art. No.	Sampling Automated
18340	DT-i-Version upgrade for DT 72x/ 82x/141x/161x
18341	ASS-8 LH autom. sampling station, PTFE coated tubing 3.0 mm, DT 72x/82x
18342	ASS-8 LH PT 100 autom. sampling station LH, PTFE coated tubing 3.0 mm
18343	ASS-8 HH autom. sampling station, tubing PTFE coated 3.0 mm
18344	ASS-8 HH PT 100 autom. sampling station, fluoropol. tubing
18345	Auto Sampling Station ASS-8 for preconfigured DT (without motor)
18348	Titanium sampling tubes for ASS-8 autom. sampling station
18349	Titanium sampling tubes for ASS-14 auto sampling station
18346	PT 100 Electronic temperature sensors (8)
18347	DFS Double Filtration Station for DT Systems
18350	Cleaning reservoir (acrylic glass) standard ASS-8
18352	Cleaning reservoir for ASS-8 sampling station w. Disso.NET
18351	Cleaning reservoir for ASS-16 for DT 141x/161x
18353	Spare part kit for DT 82x w. ASS-8
18354	Spare part kit, DT82x w. ASS-8 autom. sampl. station & 8 temp.sensors

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

General Options

Dissolution Systems

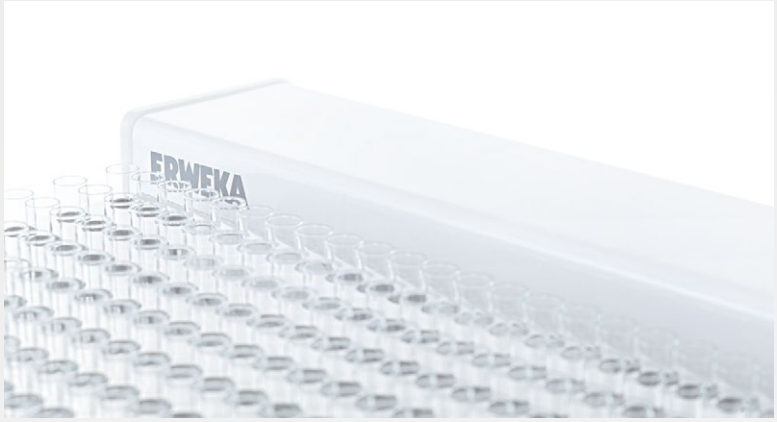
Art. No.	Filtration
18497	AFC 825 - 12 V membrane filter exchange system for 6 stations
18499	AFC 825 - 16 V membrane filter exchange system for 8 stations

AFC automatic membrane filter exchange system

Art. No.	FRL sample collector
18506	Titanium filling tubes for FRL 820/824
18507	Rack for 26 x 8 glass tubes, 12 ml, including 250 glass tubes
18508	Rack for 18 x 8 glass tubes 25 ml, including 150 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.	QA Documents
18529	IQ/OQ/PVT documents for Offline System
18530	IQ/OQ/PVT documents for Online System
18531	IQ/OQ/PVT documents for On-/Offline System UV-Vis



Sampling into UV-Vis glass tubes

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

Art. No.	Cuvettes for UV/Vis
18515	Cuvette, 0.1 mm path length
18516	Cuvette, 0.2 mm path length
18517	Cuvette, 0.5 mm path length
18521	Cuvette, 10 mm path length, flow-through optimised (standard)
18518	Cuvette, 1 mm path length
18519	Cuvette, 2 mm path length
18520	Cuvette, 5 mm path length
19945	All-quartz cuvette with two optical path lengths, 10 and 1 mm
18522	Cuvette, 20 mm path length, (only AGILENT)

Art. No.	Others
18523	Pre-heating unit for substitute media (offline systems only)
23172	pH meter Metrohm

Advanced media preparation in less than 15 minutes

MediPrep 820 Series

Highlights

- 100% USP/EP/JP compliant
- 8 liters media for dissolution testing
- Automatic cleaning
- Printer support
- Automatic degassing
- Gravimetrically controlled filling
- Foaming media possible

The ideal companion to our dissolution systems

The MediPrep 820 series offers quick and easy preparation of up to 8 liters dissolution media in less than 15 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.

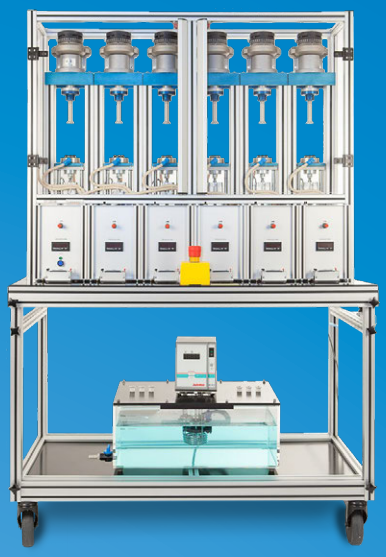
The MediPrep 820 provides one inlet for premixed media and one outlet for waste water. In comparison, MediPrep 821 and 822 offer additional inlets for media concentrates or premixed media. To prevent cross contamination, an automated cleaning procedure is integrated.

Art. No.	MediPrep 820
18605	MediPrep 820 with one inlet
18606	MediPrep 821 with one additional inlet for concentrates/premixed media
18607	MediPrep 822 with two additional inlets for concentrates/premixed media

WORLD EXCLUSIVE!

Chewing Gum Tester

DRT



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

The chewing gum test apparatus is used to chew 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.

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.

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

Highlights

- Up to 6 test stations
- Temperature controlled water bath
- Movement by pneumatic cylinder with compressed air
- Mobile cart
- Easy cleaning

Multiple media pH change dissolution testing for USP 3 and 7

RRT 10 BioDis

Different tools available

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 thus 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).

The RRT 10 is 100 % compliant to the USP/EP/JP standards and available as either USP method 3, USP method 7 or as a combination device of both USP methods 3 and 7. It comes with an external flow-through heater, which minimizes vibrations to the device. Moreover, the unit offers a mobile touch display, which is easy to use and provides convenient control. 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

	USP 3	USP 7	USP 3 & USP 7
Height of stroke	100 mm	20 mm	100 mm & 20 mm (changeable)
Vessel types	**300 ml & 1000 ml** for reciprocating cylinder	**50 ml, 100 ml, 300 ml, 1000 ml** for different types of tools	**50 ml, 100 ml, 300 ml, 1000 ml** for different types of tools
User changeable method	-	-	✓

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

USP 4 Flow-Through Cell

Dissolution tester for long-term tests and/or with high amount of media

DFZ 720 Series

The ERWEKA flow-through cell dissolution tester was developed for products that require long-term tests (e.g. implants) and/or need a high amount of media due to low solubility.

In the configuration as a closed system the flow-through cell enables performing of dissolution tests with a low amount of media in order to achieve the necessary testing environment as internationally required. Thanks to the possibility of easy pH changes, the flow-through cell is the perfect unit for IV/IVC testing. It is controlled by a PC with the Disso.NET USP 4 dissolution software.

Available as:

- **Stand-alone**
- **Closed Offline System**
- **Open Offline System**

Art. No.	USP 4 DFZ 720 Flow-through cell
18563	DFZ 720 Stand-Alone flow-through cell with HKP 720
18564	DFZ 720 Stand-Alone flow-through cell with HKP 720 + PT 100
18565	DFZ 720 Stand-Alone flow-through cell with HKP 720 + 7x3 way valve
18566	DFZ 720 Stand-Alone flow-through cell with HKP 720 + PT 100 + 7x3 way valve
18567	DFZ 720 Stand-Alone Flow-through-cell DFZ 720 with IPC 8
18568	DFZ 720R Stand-Alone Flow-through-cell with IPC 8 + 7x3 way valve

Highlights

- 100% USP/EP/JP compliant
- Controlled by Disso.NET USP 4
- Vast variations of cells
- Independent closed flow-through system

Different cells for different purposes

Accompanying our Flow-Through Systems, we offer several different cells for different purposes – from the standard tablet cell to granulate & powder cells to cells for implants, suppositories and stents.


Tablet cell 12.00 mm


Tablet cell 22.6 mm


Granulate & Powder Cell


Implant cell


Suppository cell


Stent cell


Tablet cell 22.6 mm with dialysis adapter


Tablet cell 22.6 mm with creme cell adapter


Tablet cell 22.6 mm with glass beads


Tablet cell 22.06 mm with glass beads

DFZ 720 Open Offline System

Infinite media testing and sample collection with the ERWEKA Open Offline Flow-Through System

Art. No.	USP 4 DFZ 720 Open Offline System
18584	Open Offline System USP 4 with piston pump HKP 720, FRL 724, PC, Disso.NET
18585	Open Offline System USP 4, piston pump HKP 720, PT 100, FRL 724, PC, Disso.NET
18586	Open Offline System USP 4 DFZ 720R, 7x3 way valve, HKP 720, FRL, PC, Disso.NET
18587	Open Offline System DFZ 720R, PT 100, 7x3 way valve HKP 720, FRL, PC, Disso.NET
18588	Open Offline System DFZ 720, IPC 8 peristaltic pump, FRL 724, PC, Disso.NET
18589	Open Offline System DFZ 720 R + 7x3 way valve, IPC 8, FRL 724, PC, Disso.NET

Features Automated Open Flow-Through System

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

DFZ 720 Closed Offline System

Features of the DFZ 720 Closed Flow-Through System

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

Extensive long-term testing with the independent Closed Flow-Through System

Art. No.	USP 4 DFZ 720 Closed Offline System
20487	Closed Offline System DFZ 720, HKP 720, IPC 8, FRL, PC, Disso.NET USP 4
20488	Closed Offline System DFZ 720, PT 100, HKP 720, IPC 8,FRL, PC, Disso.NET
20489	Closed Offline System DFZ 720R, 7x3 way valve, IPC 8, FRL, PC, Disso.NET
20490	Closed Offline System DFZ 720R, PT100 7x3 way valve, IPC, FRL, PC+Disso.NET

Full dissolution software solution for Flow-Through Cell

Disso.NET USP 4

The ERWEKA Disso.NET USP 4 software is the perfect 21 CFR Part 11 compliant companion to our USP 4 systems. The software offers support of all USP/EP dissolution cells used in our USP 4 systems. It also supports cells for special applications (e.g. dialyse cell) and visual guides for formulation placing in the respective cells.

Disso.NET USP 4 helps you with standard USP 4 dissolution jobs, handles qualifying tasks and provides control over each single function and connected device (e.g. connected pump, Flow-Through Cell, sample collector and/or UV-VIS spectrophotometer). Our audit trail generates a detailed protocol of all events and time. The software includes an easy to handle method editor for highest safety in GMP environment. After finishing the dissolution test, Disso.NET USP 4 creates reports with your corporate logo as PDF-file and/or exports your results (e.g. as XML-file).

Highlights

- 100% — Full audit trail according to 21 CFR Part 11
- Disso.NET — For DFZ 720
- Special version for USP 4 systems
- MS SQL Database
- Advanced report generation

Full control with Disso.NET USP 4 software

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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