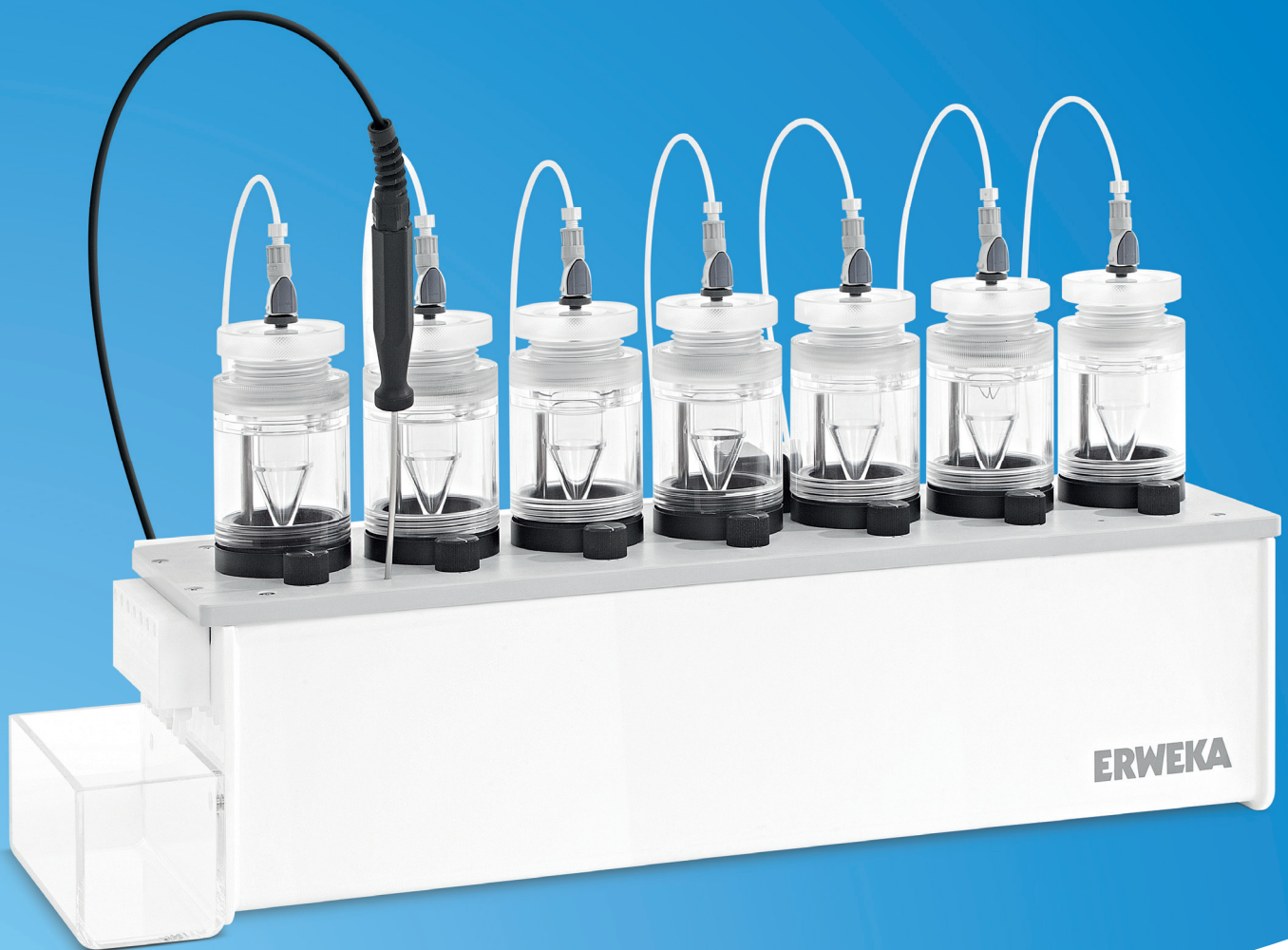


# USP 4 DFZ II

USP 4 Flow-Through Systems



**ERWEKA**

# 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 implementation of dissolution tests. The new 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 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.

## Increased 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 & 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.

100%

100% USP/EP/  
JP compliant



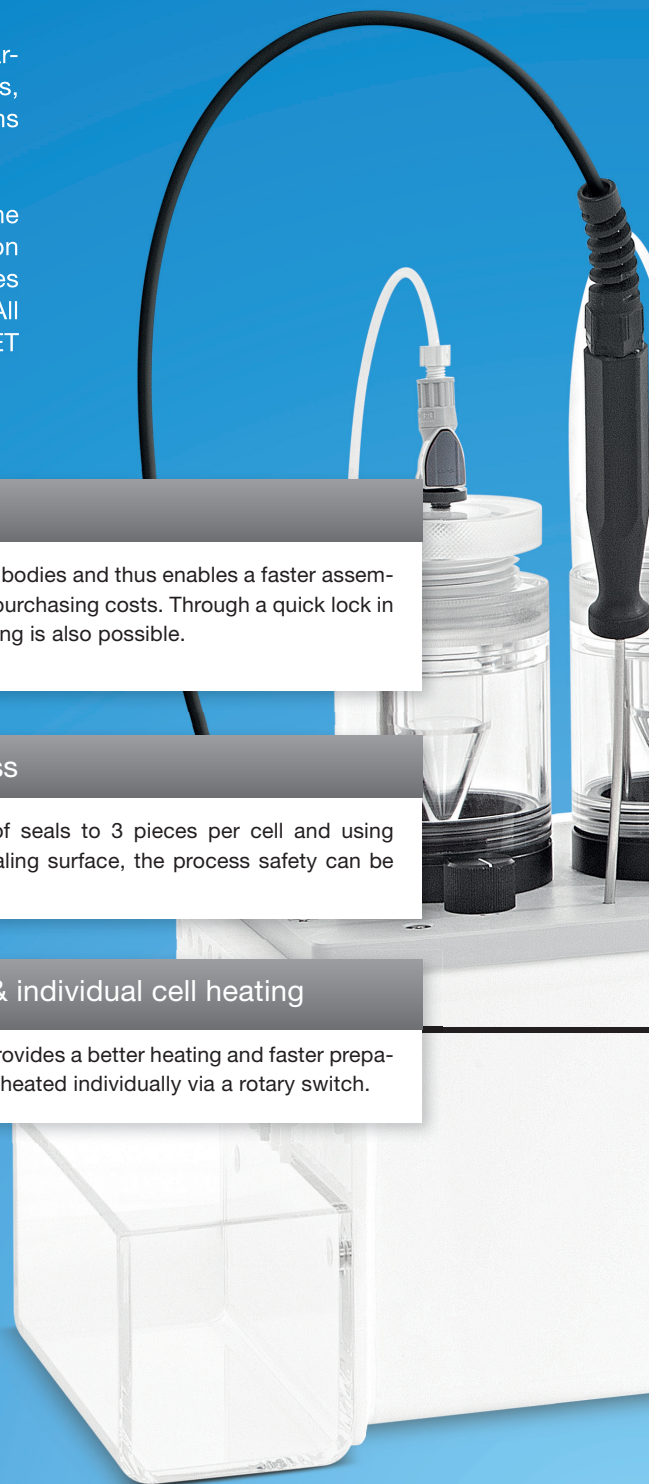
Variety of different  
cells available



Controlled by  
Disso.NET USP 4



Independent, closed  
flow-through system

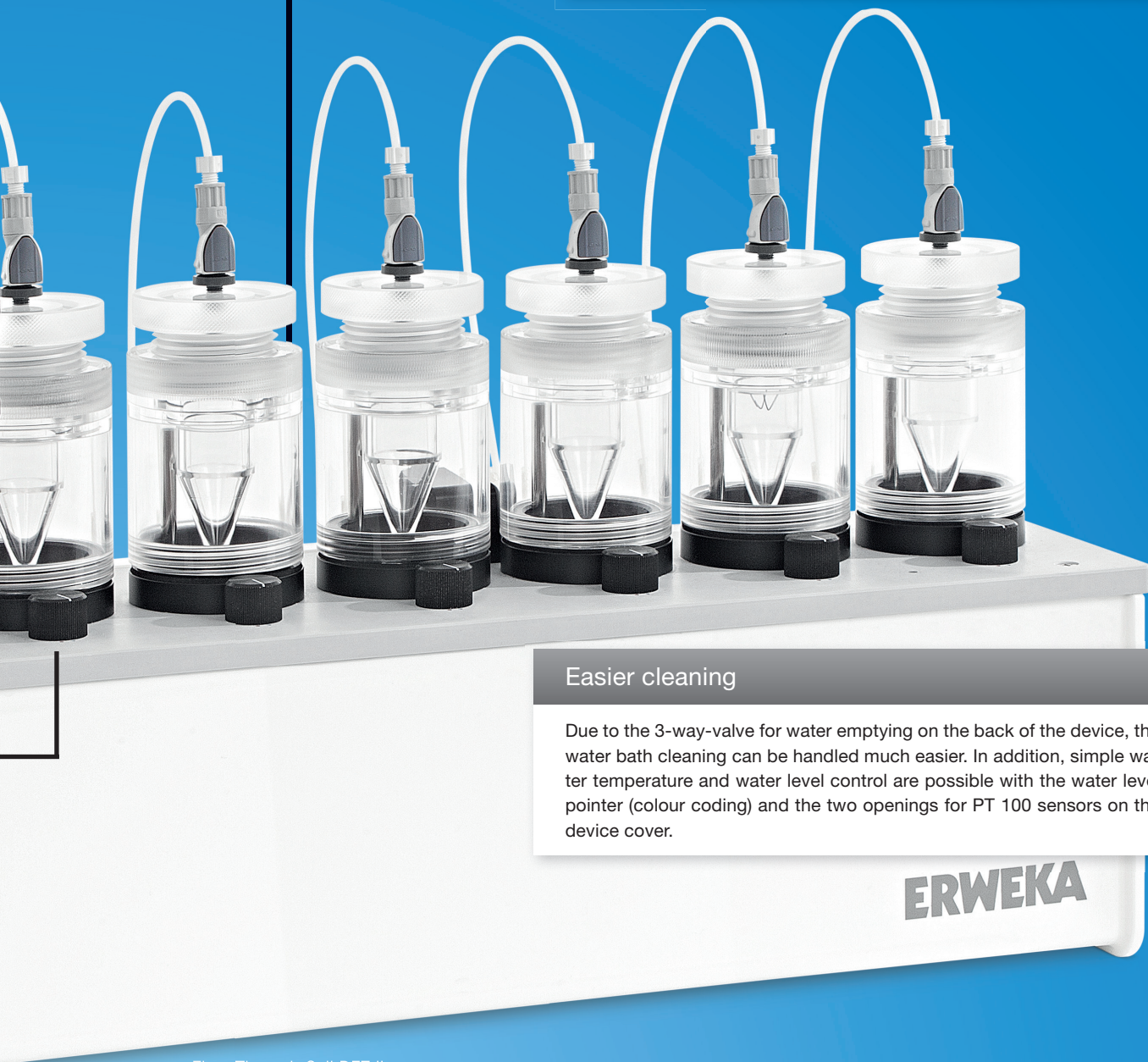






### Compact & corrosion-resistant housing

The smaller 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.

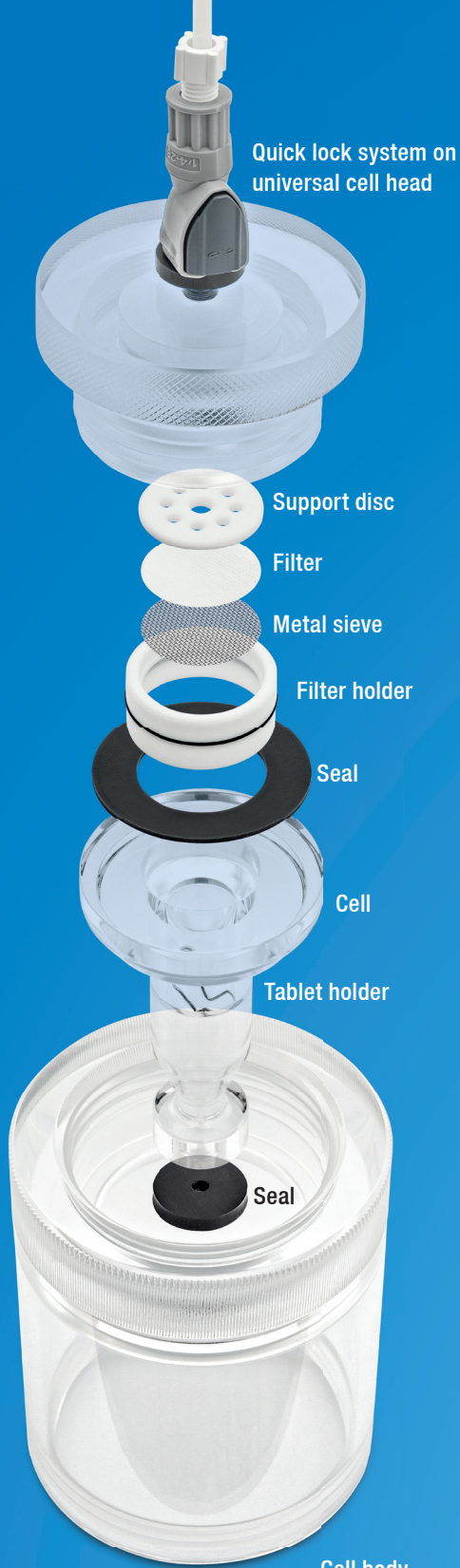


### Easier cleaning

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 PT 100 sensors on the device cover.

Flow-Through Cell DFZ II

**ERWEKA**



## Advanced, non-leaking Cell design

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

The standardized cell head fits all offered cell bodies and facilitates along with the new standardized flat seals (only 3 pieces per cell: connection, head and body) handling and assembly of the cells. The optimized cell bodies with decreased cell wall thickness guarantee an improved cell heating.



Quick lock system on the cell head allows instant tube removing.

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

### Highlights



Variety of different cells available



100 % USP/EP/JP compliant



Standardized cell head

Tool for removing the filter holder





# Different cells for different purposes



Tablet cell 12 mm



Tablet cell 22.6 mm



Granulate & Powder cell



Implant cell



Suppository cell



Stent cell



Tablet cell 22.6 mm  
with one-way  
dialysis adapter



Tablet cell 22.6 mm  
with cream adapter



Tablet cell 22.6 mm  
with glass beads &  
tablet holder



Tablet cell 22.6 mm  
with glass beads &  
without tablet holder



Special temperature calibration head

# Full dissolution software solution for the Flow-Through Cell

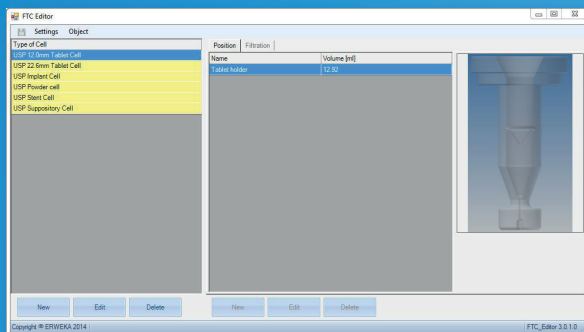
## Disso.NET USP 4

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. After finishing the dissolution test, Disso.NET USP 4 creates comprehensive reports (as PDF-files) and can export all results in various formats (e.g. as XML-file).

### Highlights

- 100% Audit trail
- Easy control of the USP 4 systems
- MS SQL Database
- Advanced report generation



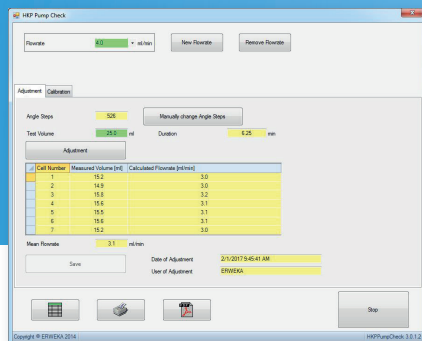
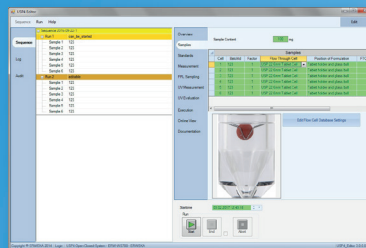
### FTC Editor

In the FTC editor the parameters of the flow-through cell can be set easily for the dissolution test:

- Type of cell
- Cell position with related volume
- Type of filter

### USP 4 Editor

With the USP 4 editor you can easily set the release parameters (e.g. sampling times) and start the dissolution test afterwards.



### HKP Pump Check

Setting of flow rate and adjustment/calibration of the ERWEKA piston pump can be easily done via the HKP Pump Check window.





Easy entry into USP 4 dissolution 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 in a system with the ERWEKA piston pump HKP 720 and the ERWEKA heater DH 2000i 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.

The stand-alone system consists of:

- Flow-through cell DFZ II + heater DH 2000i
- Piston pump HKP 720

### Highlights

100% 100% USP/EP/JP compliant

Flow-through cell with 7 test stations

Simple release testing with manual sampling



Long-term testing with automated UV/VIS analytic

## USP 4 Closed Online System

The closed ERWEKA offline flow-through cell system is excellently suited for testing low-dose formulations with sustained release (e.g. implants). It allows performing comprehensive long-term dissolution tests with small media volumes.

A fixed media volume (100 - 1000 ml) is continuously led via the ERWEKA media transfer station LMT 2 in a circle through the system and pumped through the flow cells. With the integrated UV/VIS analytic, samples can be automatically drawn from the media reservoir at software controlled time points. This allows users to draw a sound conclusion about the dissolution process.

After the test, the closed system provides the opportunity to analyze in detail the cumulative release at the considered point in time.

### The system configuration consists of:

- Flow-through cell DFZ II + heater DH 2000i
- Piston pump HKP 720
- UV/VIS analytik (e.g. Shimadzu UV-1900)
- Peristaltic pump IPC 8
- Media transfer station LMT 2
- Controller with Disso.NET USP 4 software

### Highlights



Comprehensive long-term testing



Connected UV/Vis analytics



Controlled by Disso.NET USP 4



Independent, closed flow-through system





Infinite media testing and sampling

## USP 4 Open Offline System

The open ERWEKA offline flow-through cell system is the perfect solution for testing poorly soluble products that need unlimited amounts of fresh media to dissolve. It also offers the opportunity to quickly and easily exchange media with different pH-values within one test run and is thus perfectly suited for IV/IVC testing.

With the ERWEKA sample collector FRL 724 representative samples are taken over a certain period for later analysis (up to 18 sampling intervals with 25 ml rack possible). Thanks to the integrated three-way valves a splitting into waste and sampling takes place here automatically.

The open system therefore enables, following the sampling, to analyze more precisely the actual release in the considered period.

### The system configuration comprises:

- Flow-through cell DFZ II + heater DH 2000i
- Piston pump HKP 720
- Sample collector FRL 724
- Controller with Disso.NET USP 4 software
- One or more medium reservoirs

### Highlights



Unlimited supply of media



Automatic sampling



Easy media-/ pH-changes



Controlled by Disso.NET USP 4



Comprehensive long-term testing

## USP 4 Closed Offline System

The closed ERWEKA offline flow-through cell system is excellently suited for testing low-dose formulations with sustained release (e.g. implants). It allows performing comprehensive long-term dissolution tests with small media volumes.

A fixed media volume (100 - 1000 ml) is continuously led via the ERWEKA media transfer station LMT 2 in a circle through the system and pumped through the flow cells. With the sample collector FRL 724 several samples are taken at different times for further analysis (different sampling intervals with different racks possible).

After the test, the closed system provides the opportunity to analyze in detail the cumulative release at the considered point in time.

### The system configuration consists of:

- Flow-through cell DFZ II + heater DH 2000i
- Piston pump HKP 720
- Sample collector FRL 724
- Peristaltic pump IPC 8
- Media transfer station LMT 2
- Controller with Disso.NET USP 4 software

### Highlights



Comprehensive long-term testing



Controlled by Disso.NET USP 4



Independent, closed flow-through system





Easy media transfer with the



## LMT 2

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

-  Optimal media distribution
-  Improved tubing



## Technical data

### DFZ II

Length/width/height	540 mm / 220 mm / 290 mm
Weight	ca. 8 kg (without media cells & water)
Number of cells	7 cells in a row
Water bath	6 liter volume, level indicator, emptying via 3-way-valve
Heating	Flow-through heater, cell warming of stations individually switchable
Connecting block	Connecting block with safety valve in each station
Temperature control	External PT100 temperature sensor; PT100 temperature sensor in each station (optional)
Test cells and inserts	<ul style="list-style-type: none"> <li>■ Tablet cell 22.6 mm (standard)</li> <li>■ Tablet cell 12 mm</li> <li>■ Suppository and capsule cell</li> <li>■ Powder &amp; Granulate cell (USP+EP)</li> <li>■ Stent cell</li> <li>■ Implant cell</li> <li>■ Gel and cream application for 22.6 mm tablet cell</li> <li>■ One-way adapter with 22.6 mm tablet cell</li> <li>■ Cleaning cell for system cleaning</li> <li>■ Temperature-calibration head</li> </ul>
Interface	RS 232 (PT 100 sensors)

### FRL 724

Height /width/depth	650 mm / 500 mm / 800 mm
Weight	25 kg
Sample vessel	Open System: 18 x 7 with 25 ml Closed System: 26 x 7 with 1.8 ml/ 4 ml / 12 ml; 18 x 7 with 25 ml
Power	100-240 V / 50-60 Hz
Interfaces	RS 232, RS 485

### LMT 2

Length/width/height	435 mm / 206 mm / 520 mm
Weight	11 kg (without media bottles)
Media vessel	500 ml (Standard); 100 ml / 250 ml / 1000 ml (optional)
Stirring principle	Magnetic stirrer with 8 stirring positions
Stirring volume	100-1000 ml per stirring position
Power	100-240 V / 50-60 Hz

### HKP 720

Height/width/depth	410 mm / 280 mm / 450 mm
Weight	22 kg
Channels	7 channels (valve-free)
Accuracy	Filling accuracy: ≤ 5 % at 25 ml
Flow rate setting	Flow rates adjustable (2.0-25.0 ml/min. at 120 strokes/min.)
Tubing	PTFE tubes with 1.6 mm inside diameter
Control	Alpha-numeric membrane keypad with LC display
Power	100 - 240 V, 200 Watt
Interface	RS 232

### IPC 8 pump

Height/width/depth	125 mm / 145 mm / 220 mm
Channels	8 channels
Control	Membrane keypad with LED display
Power	230 V / 50-60 Hz 115 V / 50-60 Hz
Interface	RS 232