ERWEKA
a VERDER company

PRODUCT BROCHURE

USP 4 DFZ II

USP 4 FLOW-THROUGH SYSTEMS

THE HIGHLIGHTS OF THE

USP 4 FLOW-THROUGH CELL DFZ II

USP Apparatus 4 (flow-through cell) dissolution testing is widely applied in pharmaceutical development and quality control to evaluate drug release under physiologically relevant conditions, particularly for complex and extended-release formulations. The ERWEKA DFZ II flow-through cell tester delivers exceptional flexibility across a wide range of applications. A broad selection of cell types supports testing of challenging formulations, including poorly soluble products and low-dose sustained-release systems. The cell design ensures outstanding leak-tight performance, while a streamlined tubing system with quick-connect fittings enables fast and straightforward setup of dissolution tests. The compact cell bodies promote efficient, uniform heating and allow individual temperature control for each position.

All USP Apparatus 4 DFZ II systems are fully controlled via Disso.NET 3.X software installed on a PC, enabling precise and efficient test management.

Standardized cell head

A universally compatible cell head fits all available cell bodies, supporting fast assembly and streamlined system configuration. The integrated quick-lock mechanism enables fast and secure tube connections.

High leak-tight performance

The design incorporates three seals per cell and flat sealing elements with an increased sealing surface, ensuring reliable operation and consistent process stability.

Compact cell bodies & individual cell heating

The compact cell body design supports efficient heating and fast cell preparation. Each cell features individual temperature control via a rotary switch, allowing flexible and precise operation.

Compact & corrosion-resistant housing

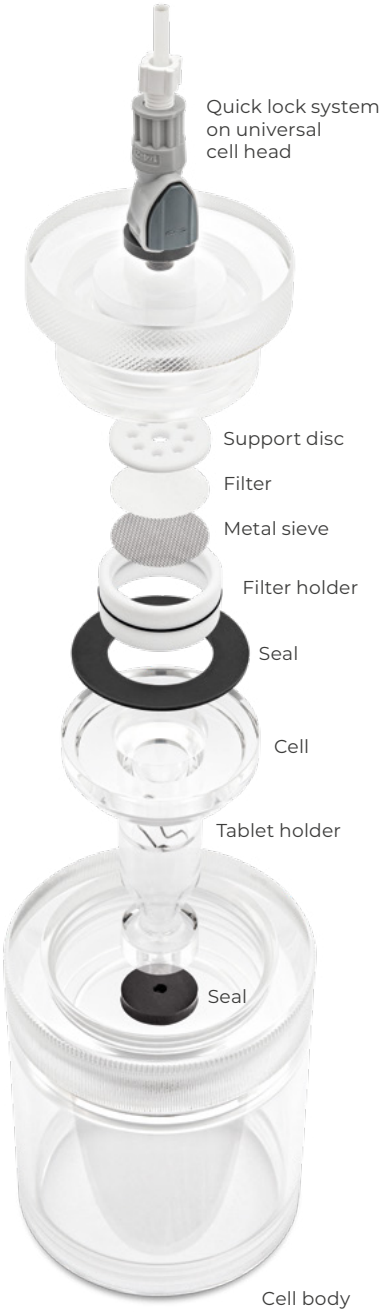
The small footprint and linear arrangement of the cells support efficient use of laboratory space while providing clear visibility of all cells at all times. A tube organizer at the rear of the system keeps tubing neatly arranged and ensures correct assignment to each cell.

Easy cleaning

The integrated three-way valve at the rear of the system enables controlled emptying of the water bath, supporting easy cleaning. Water temperature and fill level can be monitored via color-coded level pointer and two dedicated openings for PT100 sensors on the device cover.

KEY FACTS

- 100% USP/EP/JP compliant
- Variety of different cells for different applications
- Controlled by Disso.NET 3.X
- Independent, closed flow-through system



ADVANCED, HIGH LEAK-TIGHT

CELL DESIGN

Accompanying our flow-through systems, we offer a wide range of cell types designed for diverse applications - from standard tablet cells to granulate and powder cells, as well as specialized cells for implants, suppositories, and stents.

The standardized cell head is compatible with all available cell bodies and, together with standardized flat seals (three parts per cell: connection, head, and body), supports straightforward handling and assembly. The cell bodies feature a reduced wall thickness that enables efficient and uniform heat transfer within the cell.

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

This cell concept enables straightforward mounting onto the DFZ II flow-through tester, supporting fast and efficient preparation and execution 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

OVERVIEW

Tablet cell 12 mm

Tablet cell 22.6 mm

Granulate & Powder cell

Implant cell

Suppository cell

Special temperature calibration head

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

FULL DISSOLUTION SOFTWARE SOLUTION FOR THE FLOW-THROUGH CELL

DISSO.NET USP 4

The ERWEKA Disso.NET software is the ideal companion for USP Apparatus 4 systems. It provides full control of all system components and supports all pharmacopoeia-compliant dissolution methods and cell configurations (USP/EP/JP), including cells for specialized applications such as cream adapters. Integrated visual guides assist with correct formulation placement in each cell type.

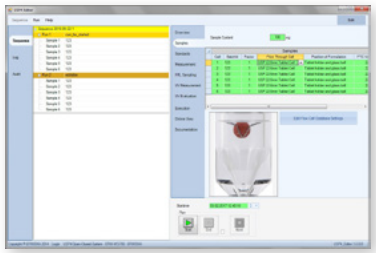
Disso.NET supports routine USP 4 dissolution testing, manages system qualification tasks, and enables precise control of all connected devices, including the pump, flow-through cell, and sample collector. The integrated method editor allows convenient and structured programming of dissolution methods, supporting reliable operation in GMP environments. Upon completion of a test, Disso.NET automatically generates comprehensive PDF reports and exports all results in various formats, including XML, ensuring seamless data handling and documentation.

HIGHLIGHTS

Easy control of the USP 4 systems

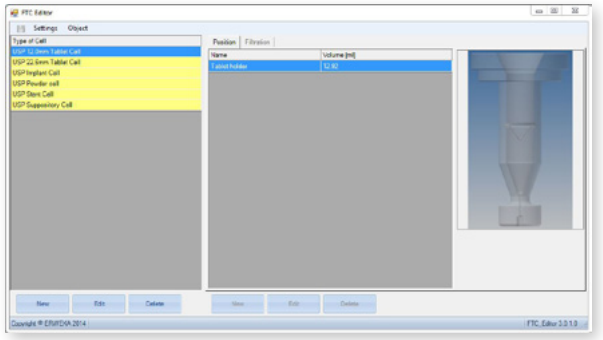
MS SQL Database

Advanced report generation



USP 4 EDITOR

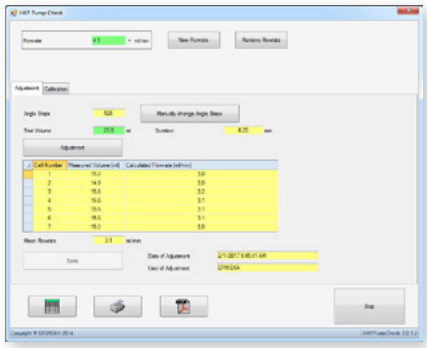
The USP 4 editor allows easily setting of release parameters (e.g. sampling times) and starting the dissolution test afterwards.



FTC EDITOR

The FTC editor allows convenient and precise configuration of all flow-through cell parameters required for dissolution testing:

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



HKP PUMP CHECK

Easily setting of flow rate and adjustment/calibration of the ERWEKA piston pump via the HKP Pump Check window.

MEDIA TRANSFER MADE EASY WITH THE

LMT 2

The compact ERWEKA LMT 2 media transfer station enables simple setup of a closed-loop system for long-term dissolution testing in accordance with USP Apparatus 4. Acting as a medium reservoir, the LMT 2 ensures consistent media mixing and reliable distribution throughout the entire test.

The tubing system with integrated tube holder and rotatable bottle caps (safety caps) supports easy handling while optimizing laboratory space. The use of standardized laboratory glass bottles as media vessels facilitates convenient media transport for storage and further analysis. Glass bottles are available in a standard size of 500 ml with optional volumes of 100 ml, 250 ml and 1000 ml. A user-friendly keypad allows precise and convenient adjustment of the stirring speed.

KEY FACTS

- 100% USP/EP/JP compliant
- Wide range of vessel sizes
- Optimal media distribution
- Improved tubing

EASY ENTRY INTO USP 4 DISSOLUTION TESTING

USP 4 STAND-ALONE SYSTEM

The ERWEKA stand-alone flow-through cell system is an ideal solution for straightforward dissolution and release testing with manual sampling. Combining the DFZ II flow-through cell tester, the HKP 720 piston pump, and the DH 2000i heater, the system provides a cost-effective and user-friendly entry into USP Apparatus 4 testing. The valve-free HKP 720 piston pump delivers highly precise medium flow through up to seven channels and automatically adjusts to the selected flow rate, ensuring reliable and reproducible test conditions. The low-vibration DH 2000i heater rapidly brings the water bath to the required temperature, providing stable thermal control throughout the testing process.

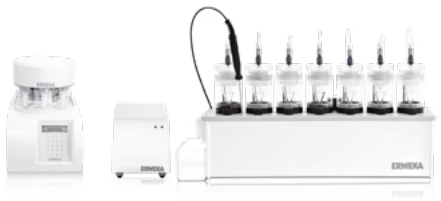
The stand-alone system consists of:

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

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 online flow-through cell system is excellently suited for testing low-dose formulations with sustained release (e.g. implants). It enables comprehensive long-term dissolution testing with small media volumes. A fixed volume of dissolution medium (100–1000 ml) is continuously recirculated through the system via the ERWEKA LMT 2 media transfer station and pumped through the flow-through cells. With integrated UV/VIS analysis, samples can be automatically taken from the media reservoir at software-controlled intervals. This allows users to gain reliable insight into the dissolution process. After the test, the closed system also enables detailed evaluation of the cumulative drug release at each selected time point.

The closed online system consists of:

- Flow-through cell DFZ II + heater DH 2000i
- Piston pump HKP 720
- UV/VIS analysis (e.g. Shimadzu UV-1900i Plus)
- Peristaltic pump IPC 8
- Media transfer station LMT 2
- Controller with Disso.NET 3.X

Comprehensive long-term testing

Independent, closed flow-through system

Connected UV/Vis analytics

Controlled by Disso.NET 3.X

INFINITE MEDIA TESTING AND SAMPLING

USP 4 OPEN OFFLINE SYSTEM

The ERWEKA open offline flow-through cell system is the perfect solution for testing poorly soluble products that require an unlimited amount of fresh dissolution medium. It also allows quick and easy medium exchange with different pH values during a single test run, making it perfectly suited for IVIVC testing.

With the ERWEKA sample collector FRL 754 representative samples are taken over a certain period for later analysis (up to 18 sampling intervals with 25 ml rack possible). Integrated three-way valves automatically direct the medium either to the sample collector or to waste. This open-system configuration enables a more precise evaluation of the actual drug release within each sampling interval, providing detailed insight into the release behavior over time.

The open offline system consists of:

- Flow-through cell DFZ II + heater DH 2000i
- Piston pump HKP 720
- Sample collector FRL 754
- Controller with Disso.NET 3.X software
- One or more medium reservoirs

COMPREHENSIVE LONG-TERM TESTING

USP 4 CLOSED OFFLINE SYSTEM

The ERWEKA closed offline flow-through cell system is excellently suited for testing low-dose formulations with sustained release properties, such as implants. It enables comprehensive long-term dissolution tests using small media volumes.

A fixed volume of dissolution medium (100–1000 ml) is continuously recirculated through the system via the ERWEKA LMT 2 media transfer station and pumped through the flow-through cells. Using the FRL 754 sample collector, multiple samples can be collected at predefined time points for subsequent analysis, with various sampling intervals and rack configurations available.

After the test, the closed system setup allows for detailed analysis of the cumulative drug release at each selected time point, providing valuable insight into the formulation's release behavior over time.

The closed offline system consists of:

- Flow-through cell DFZ II + heater DH 2000i
- Piston pump HKP 720
- Sample collector FRL 754
- Peristaltic pump IPC 8
- Media transfer station LMT 2
- Controller with Disso.NET 3.X software

HIGHLIGHTS

- Comprehensive long-term testing
- Controlled by Disso.NET 3.X
- Independent, closed flow-through system
- Unlimited supply of media
- Automatic sampling
- Easy media-/ pH-changes

COMPREHENSIVE ON-/OFFLINE DISSOLUTION TESTING

USP 4 CLOSED ON-/OFFLINE SYSTEM

The ERWEKA closed USP 4 on-/offline flow-through cell system combines the benefits of continuous online monitoring with the flexibility of automated offline sampling. It is particularly well suited for the investigation of poorly soluble APIs, low-dose formulations, and extended-release dosage forms such as implants and other modified-release products.

During dissolution testing, samples can be collected automatically at predefined time points using the FRL 754 Fraction Collector and stored for further analysis. In addition, the system can be coupled with an online UV/VIS analysis solution to monitor the drug release profile in real time. By combining both approaches, users benefit from maximum flexibility in the characterization of complex release profiles and gain a comprehensive data set for long-term dissolution studies.

The USP 4 closed on-/offline system consists of:

- Flow-through cell DFZ II + heater DH 2000i
- Piston pump HKP 720
- Sample collector FRL 754
- UV/VIS analysis (e.g. Shimadzu UV-1900i Plus)
- Peristaltic pump IPC 8
- Media transfer station LMT 2
- Controller with Disso.NET 3.X software

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	I Tablet cell 22.6 mm (standard) I Tablet cell 12 mm I Suppository and capsule cell I Powder & Granulate cell (USP+EP) I Stent cell I Implant cell I Gel and cream application for 22.6 mm tablet cell I One-way adapter with 22.6 mm tablet cell I Cleaning cell for system cleaning I Temperature-calibration head
Interface	RS 232 (PT 100 sensors)

FRL 754

Height /width/depth	583 mm / 515 mm / 702 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	110-240 V / 50-60 Hz
Interfaces	RS 232, RS 485

LMT 2

Lenght/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 (4.0-16.0 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

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VERDER

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