

USP 4

Flow-Through Cell Systems

For products which require long term tests and / or high amount of media due to low solubility



ERWEKA

USP 4 Stand-Alone System



The Flow-Through-Cell

The ERWEKA Flow-Through cell dissolution tester is developed for products which require long term tests (i.e. implants) and / or need a high amount of media due to low solubility. In configuration as a closed system the Flow-Through cell enables dissolution tests with a low amount of media in order to achieve the necessary testing environment as internationally required. Due to the possibility for 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.

Main System Components

- ✓ DFZ 720 Flow-Through cell
- ✓ HKP 720 Pump
- ✓ PC with Disso.net USP 4 Software

Features HKP 720 Pump

- ✓ 100% USP conform valve-free piston pump
- ✓ Automatic setting of different flow rates 2 - 32 ml / min
- ✓ 7-channels
- ✓ High accuracy $\leq 5\%$
- ✓ Pump heads made of inert ceramic material

Features DFZ 720

- ✓ Flow-Through cell with 7 test stations
- ✓ Each cell is equipped with an individual open/closing head with filters
- ✓ Heating of the cell by double-jacket holder
- ✓ Heating of the dissolution media by internal spiral made of stainless steel
- ✓ Support plate and cell holder made of chemical resistant material
- ✓ Integrated blockage controller
- ✓ Individual cellhead of the cells with independant closing mechanism
- ✓ Small footprint
- ✓ Controlled by Disso.net PC-Software
- ✓ Easy cleaning of water bath

Features DH 2000i Heater

- ✓ 1500 W flow-through-heater
- ✓ Low vibrations
- ✓ 2 independant temperature sensors

| USP 4 Flow-Through Cell | Temperature measurement in each cell | 7x3-way-valve for individual control of each cell | Piston pump |
|-------------------------------------|--------------------------------------|---|-------------|
| DFZ 720 | - | - | HKP 720 |
| DFZ 720 | PT 100 | - | HKP 720 |
| DFZ 720R (<i>in-line version</i>) | - | ✓ | HKP 720 |
| DFZ 720R (<i>in-line version</i>) | PT 100 | ✓ | HKP 720 |

Disso.NET USP 4

Full dissolution software solution for Flow-Through-Cell

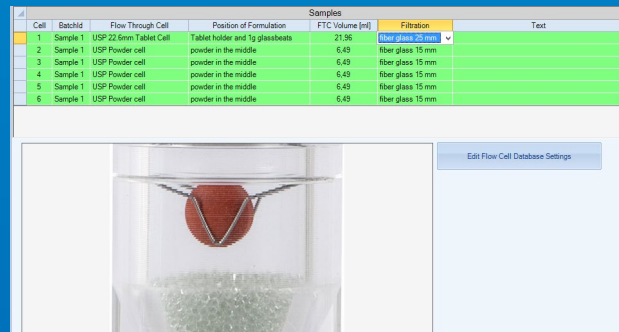
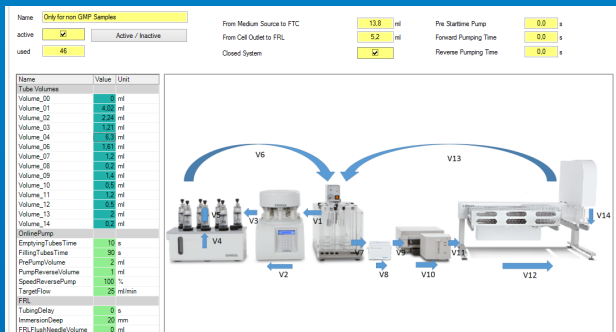


The ERWEKA Disso.net software is the perfect 21 CFR Part 11 compliant companion to our USP 4 systems. The software offers support of all USP / EP dissolution cells used in our USP 4 systems. It also supports cells for special applications (e.g. dialyse cell) and visual guides for formulation placing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

Disso.net 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 recording 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).

General Features

- ✓ Support for computer based ERWEKA Flow-Through-Cell with different system configurations
- ✓ Configurations for Closed and Open systems can be easily defined, controlled and upgraded by modular structure
- ✓ Visual support of handling of different cells according placement of the formulation
- ✓ Easy approach from top to bottom
- ✓ MS SQL database with local or network installation
- ✓ Global management of user, methods, reports, etc.
- ✓ Reliable backup and restore functions
- ✓ Multi user support with different user roles (operator, senior operator, administrator) and single permissions
- ✓ Auto log off
- ✓ Language support for English, German
- ✓ Multiple System Suitability Tests for highest reliability
- ✓ Control and configure all connected devices
- ✓ Handling of the system with multitasking JobController
- ✓ Fully documented according to 21 CFR 820
- ✓ Full audit trail according to 21 CFR Part 11 including date, time stamp, user ID
- ✓ Calculation of dissolution profiles via UV-measurement
- ✓ GMP conform data correction with automatic rebatch of results
- ✓ Integrated workflow for approval and review of reports before publishing (paperless lab)
- ✓ Report generation with custom logo
 - Compact analytical report (default report with all relevant data)
 - Method data
 - Calibration data
 - Raw data



USP 4 Open Offline System



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

The Open System is the perfect solution for tests which require an unlimited supply of fresh media, e.g. low soluble drug substance.

The sample collector FRL collects the complete or representative sample over a certain time for storage and later analysis. Due to integrated 3-way valves the system can automatically split for waste and sampling purposes.

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

Main System Components

- Flow-Through cell DFZ 720 + heater
- HKP 720 piston pump
- Sample Collector FRL 724
- PC with Disso.net USP 4 Software

Features Piston Pump HKP 720

- ✓ 100% USP conform valve-free piston pump
- ✓ Automatic setting of different flow rates 2 - 32 ml / min.
- ✓ 7-channels
- ✓ High accuracy $\leq 5\%$
- ✓ Pump heads made of inert ceramic material

Features Sample Collector FRL 724

- ✓ Up to 26 rows for extended release formulation testing
- ✓ Needles available in stainless steel or titanium for sensitive APIs
- ✓ Glass tubes (25 ml)

Features Flow-Through-Cell DFZ 720

- ✓ Flow-Through cell with 7 test stations
- ✓ Each cell is equipped with an individual open/closing head with filters
- ✓ Heating of the cell by double-jacket holder
- ✓ Heating of the dissolution media by internal spiral made of stainless steel
- ✓ Support plate and cell holder made of chemical resistant material
- ✓ Integrated blockage controller
- ✓ Small footprint
- ✓ Controlled by Disso.net USP 4
- ✓ Easy cleaning of water bath

Recommended configurations

| USP 4 Flow-Through Cell | Optional Temperature Measurement PT 100 | 7x3-way-valve for individual control of each cell | Pump | Optional VS 480 media changer | Sample collector | System control |
|-----------------------------------|---|---|---------|-------------------------------|------------------|-------------------------|
| DFZ 720 | - | - | HKP 720 | ✓ | FRL 724 | PC with Disso.net USP 4 |
| DFZ 720 | ✓ | - | HKP 720 | ✓ | FRL 724 | PC with Disso.net USP 4 |
| DFZ 720R <i>in-line system</i> | - | ✓ | HKP 720 | ✓ | FRL 724 | PC with Disso.net USP 4 |
| DFZ 720R <i>in-line system</i> | ✓ | ✓ | HKP 720 | ✓ | FRL 724 | PC with Disso.net USP 4 |



The DFZ 720R is used in combination with the 7x3-way-valve for individual control of each cell.

USP 4 Closed Offline System



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

The Closed System is the perfect solution for tests which requires low media volume for long term dissolution tests and / or to increase sensitivity of the analytical method, e.g. implants.

Features Closed Flow-Through System

- ✓ Specific amount of minimum 2 ml to maximum 32 ml of media is pumped through the cell continually
- ✓ Media transfer station LMT with 7x 1000 ml vessels
- ✓ Fully USP compliant
- ✓ IPC 8 peristaltic pump or syringe pump SP for automated sampling
- ✓ Fraction collection with 3-way valves
- ✓ Long duration test runs with optimized media evaporation
- ✓ Media replacement possible

Main System Components

- DFZ 720 Flow-Through cell + heater
- HKP 720 piston pump
- Sample Collector FRL 724
- Peristaltic pump IPC 8 or syring pump SP
- LMT 720 closed-loop unit
- PC with Disso.net USP 4 Software

Features FRL 724

- ✓ Easy access to sample tubes
- ✓ Easy to clean
- ✓ Up to 26 rows for extended release formulation testing
- ✓ Integrated cleaning procedure
- ✓ Needles available in stainless steel or titanium for sensitive APIs
- ✓ Glass tubes (25 ml)
- ✓ Automated flush routine between sampling intervals
- ✓ Gentle and precise spindle drive
- ✓ Movable trays provide easy exchange of different racks

Features Closed-Loop Unit LMT 2

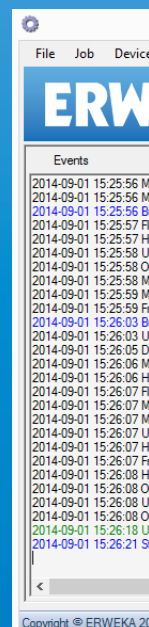
NEW!

- ✓ New, bathless heating
- ✓ Rotatable tube mounting on bottle top prevents entangled tubes
- ✓ Easier to use due to holding stand for tubes
- ✓ 300 ml, 500 ml or 1000 ml vessels available
- ✓ Continuous media stirring by magnetic stirrers

The new LMT 2 with bathless heating and 500 ml vessels (other vessel sizes available as option) with new, rotatable tube mounting (safety cap) for clear and distortion-free wiring of the tubes.



Flow-Through Cell: USP 4 Closed Offline System



Recommended configurations

| USP 4 Flow-Through Cell | Optional Temperature Measurement PT 100 | Optional 7x3-way-valve for individual control of each cell | Pump | LMT 2 unit | Sample collector | Pump for FRL | System control |
|-----------------------------------|---|--|---------|------------|------------------|--------------|-------------------------|
| DFZ 720 | - | - | HKP 720 | LMT 2 | FRL 724 | IPC 8 | PC with Disso.net USP 4 |
| DFZ 720 | ✓ | - | HKP 720 | LMT 2 | FRL 724 | IPC 8 | PC with Disso.net USP 4 |
| DFZ 720R <i>in-line system</i> | ✓ | ✓ | HKP 720 | LMT 2 | FRL 724 | IPC 8 | PC with Disso.net USP 4 |
| DFZ 720R <i>in-line system</i> | - | ✓ | HKP 720 | LMT 2 | FRL 724 | IPC 8 | PC with Disso.net USP 4 |

ERWEKA JobController

Show Help

ERWEKA

Disso.Net USP4

MeasuringStation: USP4 - Labor

MeasuringStationType: Disso.Net USP4

Building device list...

Flow Through Cell Station: added

Reater: added

SP4 Pump: added

Online Pump: added

Medium Source: added

Medium Reservoir: added

ReactionCollector: added

Building job list...

SP4 Job: added

Dissolution Report: added

Maintenance: added

KP Pump Check: added

Flow Through Cell Station: Erweka - ?

Medium Reservoir: Erweka - ?

Medium Source: Erweka - MediaChanger Manual - 1

SP4 Pump: Erweka - HKP

Reater: Erweka - ID60 - unknown

Reaction Collector Check: added

Reater Check: added

Online Pump Check: added

SP4 Pump: SwapPumpDirection True

Online Pump: Ismatec - IPC 405 - 0405

User logged in: ERWEKA

Starting ready

Volume_14

0.2 ml

OnlinePump

EmptyingTubesTime

10 s

FillingTubesTime

90 s

PrePumpVolume

2 ml

PumpReverseVolume

1 ml

SpeedReversePump

100 %

TargetFlow

25 ml/min

FRL

TubingDelay

0 s

ImmersionDeep

20 mm

FRLFlushNeedleVolume

0 ml

LastDrops

0 ml

Disso.Net 3.0.0.0

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The new USP4 version of our advanced Disso.NET software allows comfortable and easy use of our USP 4 systems.

Sampling Unit

From Medium Source to FTC

13,8 ml

Pre Starttime Pump

0,0 s

From Cell Outlet to FRL

5,2 ml

Forward Pumping Time

0,0 s

Closed System

☒

Reverse Pumping Time

0,0 s

Volume 5 is defined in the USP4 Editor

SamplingUnit 3.0.0.0

Flow-Through-Cells USP 4

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 22.6mm
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



Tablet holders type A 22,6 mm and type B 12mm

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Technical specifications of products described are stated without warranty and subject to change any time without further notice.
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