

Dissolution On-/Offline System with **HPLC**

Semi-automated dissolution testing with HPLC analysis



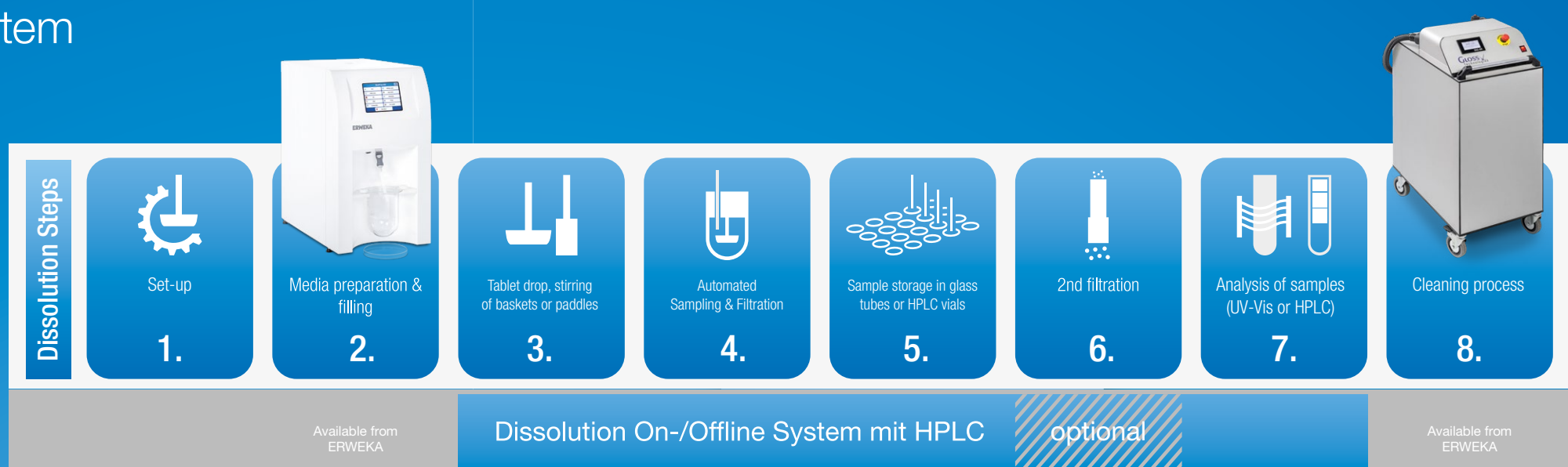
ERWEKA

Semi-automated dissolution system with HPLC analysis

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

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

- 100% USP/EP/JP compliant
- 21 CFR Part 11 conform in conjunction with Disso.NET software
- CTC sample collector and sample storage for HPLC
- 5 of 8 dissolution steps are automated



Dissolution Tester DT 720

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

PVP 820 Pump

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

Double filtration with AFC 825

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



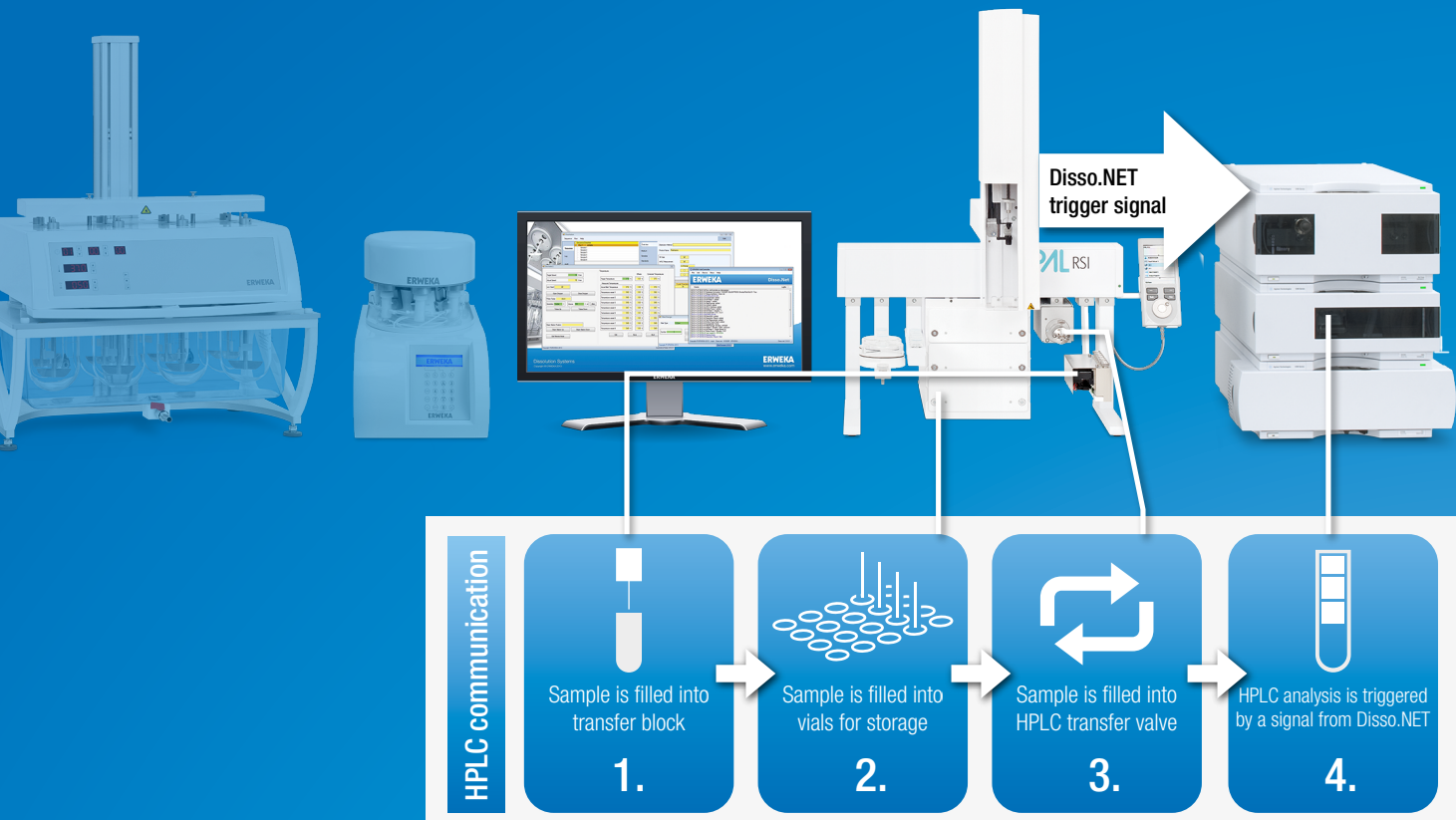
HPLC sample collection & analysis

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

Disso.NET Software

Our advanced dissolution software solution Disso.NET takes over full control of the dissolution system and offers extensive functions, enhanced user management and diverse data export options (e.g. LIMS connection).

HPLC analysis device not included in system configuration! (Support of various manufacturers) **NOTE**



A simple way to HPLC analysis

After dissolution testing* with the DT 720 and double filtration with the PVP 820 pump and the AFC 825, the medium is transferred to the HPLC sampler. There, the medium is first filled in a transfer block (PEEK block), and afterwards distributed into appropriate vials. If required, the samples can be diluted for immediate analysis or cooled** and stored temporarily against UV radiation for later analysis.

The HPLC analysis starts as soon as a sample is filled into the HPLC valve of the sampler and a trigger signal is sent by the Disso.NET to the HPLC device. The analysis as well as the evaluation are done by the analysis software of the corresponding HPLC manufacturer on a separate PC. As the analysis times of the samples are defined beforehand via the Disso.NET software, the sampler steadily passes the samples to the HPLC device (even after the termination of the release). Consequently, the dissolution test with HPLC analysis can be performed automatically without an operator (e. g. also at night).

After the HPLC analysis, the results are displayed on a separate PC.

*Also during the test, at certain sampling times.
** Option

Not included in system configuration:

- HPLC analysis device
- HPLC analysis software (on a separate PC)

Our Dissolution On-/Offline System with HPLC supports different manufacturer (e.g. Agilent, Shimadzu, Waters).

NOTE

Full dissolution software solution

Disso.NET

The ERWEKA Disso.NET software is the perfect companion for the semi-automated dissolution HPLC On-/Offline systems. The software takes over full control and offers support for all test methods, that can be applied with the dissolution system with HPLC analysis.

Disso.NET helps you with standard dissolution jobs, handles qualification tasks and provides control over each single function of the connected devices (e.g. DT, PVP and auto sampler). In addition, the software includes an easy to handle method editor for comfortable programming of dissolution methods (for highest safety in GMP environment). The 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 creates comprehensive reports (as PDF-files or printouts) and can export all results in various formats (e. g. as XML file).

Highlights

- 100% Audit trail
- Easy control of the On-/Offline systems
- MS SQL Database
- Advanced report generation

Upon request data export to LIMS systems!

NOTE

Full control with Disso.NET software



Comprehensively configurable

Our systems with HPLC analysis

Our semi-automatic Dissolution On-/Offline Systems with HPLC distinguish themselves in particular through a high degree of automation and flexibility. This enables you to specify your HPLC system tailored to your individual needs.



We offer the following configurations (Note - HPLC analysis device is not included):

- HPLC On-/Offline Dissolution System with DT 720, PVP 820 Pump and AFC 825 (recommended)
- HPLC On-/Offline Dissolution System with DT 720, IPC 8 Pump and AFC 825
- Optional: Connection of 2 DTs (including 2 x PVPs or IPCs) to a HPLC Sampler with 2 transfer blocks (PEEK blocks)

Reliable and flexible collection of samples

HPLC Sampler

With the HPLC sampler samples can be collected and stored reliably and flexibly for subsequent HPLC analysis. It excels through its mechanical precision and its compact design. In addition, the open and modular unit design enables the exchange of single components within a short period of time.

If required, the collected samples can be diluted or stored temporarily cooled and UV-protected for later analysis. The HPLC sampler automatically detects the correct position of the injection syringe, thus ensuring a quick, reproducible injection of the samples into the vials. In this way, potential mixing of the individual samples can be avoided.

The sampler is easily controlled by the Disso.NET software.



Media replacement with membrane filters

Automatic Filter Changer AFC 825

We recommend the implementation of a second filtration to avoid contamination or damage of the HPLC column due to particles, thus improving the accuracy of the HPLC analysis. In combination with the high-precision, practically maintenance-free PVP pump, we offer an additional device: the automated filter changer AFC 825.

The AFC 825 enables the automatic exchange of the used membrane filters (e. g. 0.22 µm, 0.45 µm) after each sampling or each test run. In addition, the media replacement can be conducted via the integrated bypass. As most of the filters are uni-directional - i.e. media is pumped in only one direction - the bypass prevents the media from being pressed back through the used membrane filters, thus avoiding the risk of filter damage.

The automated filter changer features a magazine with eight positions for membrane filters (max. 8x25 filter) and comes in two configurations:

- AFC 825 with 12 valves for 6 stations
- AFC 825 with 16 valves for 8 stations

Highlights



No plugging of the HPLC column!



Automated filter change



Integrated in Disso.NET



Technical data

DT 720 Series

Appliance details	Dissolution tester for USP methods 1 (Basket), 2 (Paddle), 5 (Paddle-over-disk) and 6 (Rotating Cylinder) with 6, 7 or 8 Test stations (726, 727, 728) in 2 lines
Vessel	1000 ml, optional: 2000 ml, temperatur sensor in each vessel; manual tablet drop magazine
Device control	LED display, for each test parameter with function keys
Compliance	100% USP/EP/JP compliant
Width/Depth/Height	830 mm (including heating) / 640 mm / 940 mm
Weight	47 kg
Rotation Speed	20 - 220 U / min.
Water bath	20 liter
Evaporation	Less than 1% (50 UpM / 1000 ml / 37° C / 24 h)
Heating	<ul style="list-style-type: none"> ■ Heating rate: 1500 W ■ Heating range: 30-50° C
Power	115 or 230 VAC, 50/60 Hz
Fuses	115/250V, 16A, 250V, 1A/115V, 2A
Interfaces	<ul style="list-style-type: none"> ■ RS 232 for PC connection ■ USB-B for firmware updates ■ USB-A printer interface for documentation of test parameter time, date, temperature etc. (optional)

AFC 825

Appliance details	Automated filter changer
Width/Depth/Height	215 mm (without filter refill) or 580 mm (with filter refill) / 200 mm (without valves) or 215 mm (with valves) / 610 mm
Filter requirements	<ul style="list-style-type: none"> ■ Pore size: 0.22 µm, 0.45 µm, 0.70 µm, 1.0 µm, 10 µm ■ Diameter: ≤ 30 mm for automation
Power	100-240 VAC +/- 10% / 50 and 60 Hz
Fuses	115 V / 250 V, 2 x 3.15 A
Interfaces	RS 232 (one), RS 485 (two)

PVP 820

Appliance details	Valve-free sample dilution pump for highly precise media transfer with 6 or 8 channels
Width/Depth/Height	280 mm / 450 mm / 410 mm
Weight	22 kg
Device control	Alphanumeric keypad with LC display
Material	Ceramic pistons, cylinders and PTFE tubes (Avoidance of absorption of medication)
Accuracy	High accuracy (+/- 1%)
Pump heads	Fine adjustment mechanism for recalibration by the operator, automatic ventilation
Output	25 ml/min. (Standard)
Power	100-240 VAC / 50/60 Hz, 100 W
Interfaces	RS 232 for external control, RS 485 interfaces, USB-A and USB-B interface, SD card, Ethernet connection

HPLC Sampler (PAL RSI)

Appliance details	Sampler
Dimensions with Standard legs (Width/Depth/Height)	600 mm / 795 mm / 770 mm
Work surface (Width/Depth/Height)	420 mm / 255 mm / 420 mm
Weight	17.8 kg
Sample capacity	2 tablet holders, up to: <ul style="list-style-type: none"> ■ 420 x 1 ml vials ■ 324 x 2 ml vials ■ 90 x 10/20 ml vials ■ 6 MT / DW discs
Sample capacity, temperature-controlled (4-40° C)	1 peltier modul, up to (with 6 DW): <ul style="list-style-type: none"> ■ 420 x 1 ml vials ■ 324 x 2 ml vials ■ 90 x 10 ml vials ■ 6 MT / DW discs