ERWEKA
a VERDER company

SEMI-AUTOMATIC DISSOLUTION TEST WITH HPLC ANALYSIS

DISSOLUTION HPLC ON-/OFFLINE SYSTEM

The ERWEKA Dissolution HPLC On-/ Offline System is the semi-automated solution for 100% USP / EP / JP compliant dissolution testing with HPLC online analysis. Up to 5 out of 8 dissolution steps can be automated by combining one of our highly qualified dissolution testers of the DT 950 or DT 9510 series 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 automatic filter changer AFC 825 can be used in combination with our maintenance-free PVP pump. In addition to precise and simple control of the entire system, Disso.NET provides an accurate record of the entire test process, from the automatic recording of the sampling time to the recording of the temperature and rotation speed in each vessel (= documentation of all system processes, Audit Trail).

SEMI-AUTOMATIC DISSOLUTION TEST WITH HPLC ANALYSIS

A SIMPLE WAY TO HPLC ANALYSIS

After the dissolution test* with the DT 950 and double filtration with the PVP 820 pump and the AFC 825, the medium is transferred to the HPLC sampler. There, it is first filled into a transfer block (PEEK block) and then distributed into appropriate vials. If required, the samples can be diluted for immediate analysis or cooled and temporarily stored against UV radiation for later analysis.

The HPLC analysis starts as soon as a sample is filled into the sampler's HPLC valve and a trigger signal is sent from Disso.NET to the HPLC device. The analysis and evaluation is carried out using the analysis software of the respective HPLC manufacturer on a separate PC. As the analysis times of the samples are defined in advance via the Disso.NET software, the sampler steadily passes the samples on to the HPLC device (even after the release has been completed). This means that the dissolution test with HPLC analysis can be carried out automatically and without an operator (e.g. even at night). After the HPLC analysis, the results are displayed on a separate PC.

PROVEN ERWEKA QUALITY THROUGHOUT

COMPONENTS

DISSOLUTION TESTER DT 950

The dissolution tester of the DT 950 series is 100% compliant with USP methods 1, 2, 5 and 6 and can be operated in both high-head and low-head mode.

PVP 820 PUMP

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

DISSO.NET

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

Disso.NET helps with standard dissolution jobs, handles qualification tasks and provides control over every single function of the connected devices (e.g. DT, PVP and auto sampler). In addition, the software includes an easy-to-use method editor for convenient programming of dissolution methods (for maximum safety in the GMP environment). The Audit Trail also creates detailed logs of all events and time periods, allowing changes to be tracked at any time. After completion of 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 files).

HPLC SAMPLER

With the HPLC sampler, samples can be reliably and flexibly collected and stored for subsequent HPLC analysis. It excels with its mechanical precision and compact design. The open and modular instrument design also allows individual components to be replaced within a short 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 and thus ensures fast, reproducible sample injection into the vials. That way, possible mixing of the individual samples is avoided.

The autosampler is easily controlled by our ERWEKA Disso.NET software.

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. 0.45 µm, 1 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 filters) and comes in two configurations:

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

OUR HPLC ANALYSIS SYSTEMS

COMPREHENSIVE CONFIGURATION

- HPLC On-/ Offline Dissolution System with DT 950, PVP 820 pump and AFC 825 (recommended)
- HPLC On-/Offline Dissolution System with DT 950, IPC 8 Pump and AFC 825
- Optional: Connection of 2 DTs (including 2 x PVPs or IPCs) to an HPLC sampler with 2 transfer blocks (PEEK blocks)
- Optional spectrophotometers: Shimadzu, Agilent, Waters
- IQ / OQ / PV documents and services available

DT 950

TECHNICAL DATA

Weight	42 kg
Dimensions (H x W x D)	850 x 650 x 650 mm
Voltage	115/230 V; 50/60 Hz
Speed	20-250 U/min
Vessel volume	400 ml / 1000 ml / 2000 ml
Interfaces	1x RS-232, 2x USB, 2x Ethernet/RJ45
Test stations (DT 956)	6 in 2 rows
Test stations (DT 957)	7 in 2 rows
Test stations (DT 958)	8 in 2 rows
USP methods	USP 1 / USP 2 / USP 5 / USP 6
Fuses	2 A
Protection class	I/EN 61140
Protection type	IP 21/IEC 529
Operation	Touchscreen 7", 800x480 Pixel
Sampling positions	High-head / Low-head / Cleaning mode
Ambient temperature during operation	+10 °C to +30 °C (ambient temperature min. -5 °C below set temperature)
Storage & Transport temp.	+5 °C to +40 °C
Relative humidity	25-80 % non condensing

DT 9510

TECHNICAL DATA

Weight	110 kg
Dimensions (H x W x D)	850 x 1062 x 650 mm
Voltage	115/230 V; 50/60 Hz
Speed	20-250 U/min
Vessel volume	400 ml / 1000 ml / 2000 ml
Interfaces	1x RS-232, 2x USB, 2x Ethernet/RJ45
Test stations (DT 9512)	12 in 2 rows
Test stations (DT 9513)	13 in 2 rows
Test stations (DT 9514)	14 in 2 rows
USP methods	USP 1 / USP 2 / USP 5 / USP 6
Fuses	2 A
Protection class	I/EN 61140
Protection type	IP 21/IEC 529
Operation	Touchscreen 7", 800x480 Pixel
Sampling positions	High-head / Low-head / Cleaning mode
Ambient temperature during operation	+10 °C to +30 °C (ambient temperature min. -5 °C below set temperature)
Storage & Transport temp.	+5 °C to +40 °C
Relative humidity	25-80 % non condensing

PVP PUMP X20

TECHNICAL DATA

Weight	28 kg (for PVP 1220/1420)
Dimensions (H x W x D)	420 x 275 x 575 mm (for PVP 1220/1420)
Voltage	115 V or 230 V, 50/60 Hz
Pump type	PVP 1220/1420 (for DT 9510)
Channels	12 or 14 (for PVP 1220/1420)
Valves	/
Accuracy	+/- 0.5 ml
System compatibility	DT Online System, DT Offline System, DT On-/Offline System
Benefits	Filtration down to 0.22 µm with a flat membrane filtration. Particularly suitable for fully automatic dissolution systems.

IPC PUMP 8/16

TECHNICAL DATA

Dimensions (H x W x D)	125 x 145 x 220 mm
Interfaces	RS 232
Channels	8 or 16
Accuracy	25 ml +/– 5%
Media replacement	Standard
Double filtration (optional)	Only when first filtration with poroplast filters. No media replacement possible when double filtration.
Required type of sample collector	FRL 654 / 754 / 854
System compatibility	DT Offline / DT Online / DT On-/Offline
Advantages	Basic pump possible with DT 950/9510, needs regular replacement of tubing

AUTOMATIC FILTER CHANGER AFC 825

TECHNICAL DATA

Dimensions (H x W x D)	610 mm x 215 mm (without filter refill) or 580 mm (with filter refill) x 200 mm (without valves) or 215 mm (with valves)
Voltage	100-240 VAC +/- 10% / 50 and 60 Hz
Interfaces	RS 232
Fuses	115 V / 250 V, 2 x 3.15 A
Filter requirements	- Pore size: 0.22 µm, 0.45 µm, 0.70 µm, 1.0 µm, 10 µm - Diameter: ≤ 30 mm for automation
Supported filters	- PALL Membrane Filter ACRODISC - Whatman Roby 25 syringe filters for robotic systems
Stations	12 valves for 6 stations / 16 valves for 8 stations