

# Dissolution UV-Vis Systems

Semi-Automated Dissolution System USP Apparatus 1, 2, 5 and 6

The ERWEKA dissolution systems are intended for dissolution testing of tablets, coated tablets, oblongs and other dosage forms for quality control and development. These systems have been designed according to the USP and EP requirements and fully conform to the safety requirements for electronic laboratory equipment.

The ERWEKA dissolution system is a flexible system that comprises different measuring and analytical equipment. Depending on the demands, various types of dissolution systems can be applied. online, offline and off-/online.



## Component Highlights

### System Highlights

- Full support of USP Methods 1, 2, 5, 6
- 100% USP/EP compliant system
- Automated sampling with automatic USP height adjustment and optional measuring of temperature in each vessel
- Automated tablet drop (option)
- Complete integration of different types of spectrophotometer
- High analytical flexibility due to additional integration of sample collector (e.g. for later HPLC measurement)
- Measuring of complete spectra
- Media replacement

### Pump Highlights

- IPC pump – reasonable price and easy to handle, inert material, 8 channel and 16 channels possible
- PVP piston pump – for double filtration down to 0.22  $\mu\text{m}$  for flat membrane filters, high precision, inert ceramic material pump heads, almost maintenance free

### Sample Collector FRL Highlights

- Up to 26 rows for extended release formulation testing
- Needles available in stainless steel or titanium for sensitive APIs
- Special procedure for handling of foaming media
- Automated flush routine between sampling intervals
- Movable trays provide easy exchange of racks

- Different racks available for glass tubes or HPLC vials
- Handling of septa-sealed HPLC vials
- Easy access to sample tubes
- Easy to clean

### Software Highlights

- Controls different types of spectrophotometer without the need of additional vendor software required
- Easy recalculation of results
- 21 CFR Part 11 compliant
- Calculation of dissolution profiles via UV-measurement
- MS SQL database with local or network installation
- Support for computer based ERWEKA dissolution systems, capable of testing USP methods 1, 2, 5 and 6
- Multiple System Suitability Tests for highest reliability
- Easy approach from top to bottom
- Semiannual check of the photometer according EP

# Dissolution UV-Vis Online System

## Standard Online System with UV-Vis Spectrophotometer

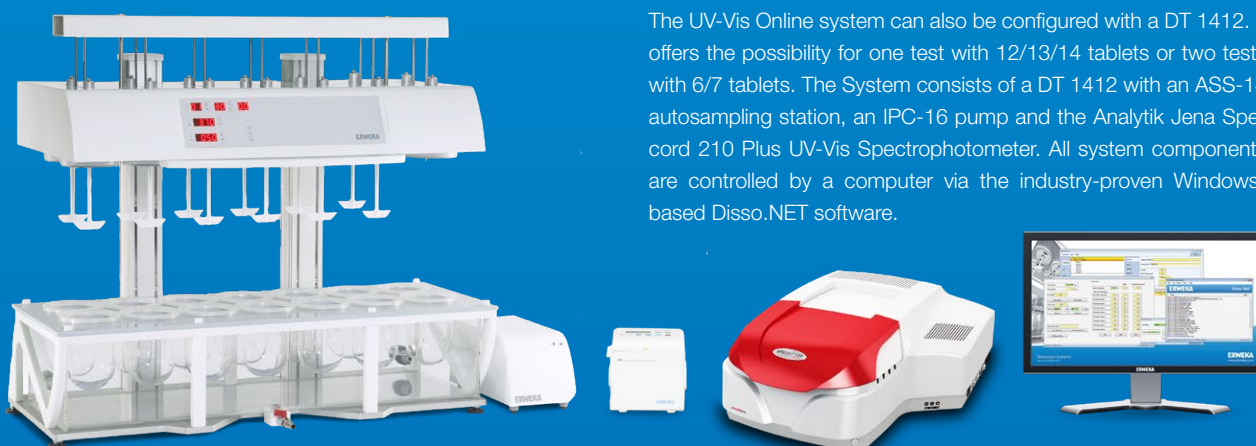
The online dissolution system consists of a DT 820, an IPC 8 and is fitted with a UV-VIS spectrophotometer for measuring absorption after testing.



| Dissolution Tester | Automatic Sampling Station | Peristaltic Pump | UV-Vis Spectrophotometer      | Disso.NET Software |
|--------------------|----------------------------|------------------|-------------------------------|--------------------|
| DT 726 / 727 / 728 | ASS-8                      | IPC 8            | Shimadzu 1800 or Agilent 8454 | ✓                  |

## DT 1412 Online System with UV/VIS Spectrophotometer

The UV-Vis Online system can also be configured with a DT 1412. It offers the possibility for one test with 12/13/14 tablets or two tests with 6/7 tablets. The System consists of a DT 1412 with an ASS-14 autosampling station, an IPC-16 pump and the Analytik Jena Specord 210 Plus UV-Vis Spectrophotometer. All system components are controlled by a computer via the industry-proven Windows-based Disso.NET software.



| Dissolution Tester | Automatic Sampling Station | Peristaltic Pump | UV-Vis Spectrophotometer       | Disso.NET Software |
|--------------------|----------------------------|------------------|--------------------------------|--------------------|
| DT 1412            | ASS-14                     | IPC 16           | Analytik Jena Specord 210 plus | ✓                  |

# Dissolution UV-Vis On-/Offline System

## On-/Offline System with DT 72x-Series

A high degree of automation and flexibility is offered by the half-automated on-/offline dissolution system. It is controlled via the fully validated ERWEKA Disso.NET software and offers automated dissolution testing, integrated UV-Vis analysis and sample collection into HPLC vials or glass tubes for reference samples or later HPLC analysis.



| Dissolution Tester             | Automatic Sampling Station | Peristaltic Pump | UV-Vis Spectrophotometer      | Sample Collector | Disso.NET Software |
|--------------------------------|----------------------------|------------------|-------------------------------|------------------|--------------------|
| DT 726 (DT 727 / 728 possible) | ASS-8                      | IPC 8            | Shimadzu 1800 or Agilent 8454 | FRL 624          | ✓                  |

## On-/Offline System with DT 1412

The DT 1412 with 12 test stations can also be configured as an UV-Vis On-/Offline system. This configuration has an ASS-14 autosampling station on top of the tester and an IPC-16 pump which connects to an Analytik Jena Specord 210 Plus UV-Vis Spectrophotometer and FRL 624-2 sample collector, all managed via PC and ERWEKA Disso.NET software.



| Dissolution Tester | Automatic Sampling Station | Peristaltic Pump | UV-Vis Spectrophotometer       | Sample Collector | PC + Disso.NET Software |
|--------------------|----------------------------|------------------|--------------------------------|------------------|-------------------------|
| DT 1412            | ASS-14                     | IPC 16           | Analytik Jena Specord 210 plus | FRL 624-2        | ✓                       |

# Technical Specifications

## Sample Collector FRL 624 / 724 / 824

Auto sample collector with 6 to 8 channels for sampling up to 26 intervals; 1 driven dosing arm with 8 stainless steel (optional Titanium) dosing needles, RS 232 interface for external control by Disso.NET software.

## Sampling tubes and HPLC vials

26x 8 glass tubes of 12 ml capacity  
 18x 8 glass tubes of 25 ml capacity  
 26x 8 HPLC vials of 1.5 ml capacity  
 26x 8 HPLC vials of 4.0 ml capacity  
 Handling of septa-sealed HPLC vials

## System Control with Disso.NET

The Disso.NET Software offers support of all methods manageable with the ERWEKA DT dissolution testers. The Software helps you with standard dissolution jobs, handles qualifying tasks and provides control over each single function and connected device.

- MS SQL database with local or network installation
- Multiple System Suitability Tests for highest reliability.
- Full audit trail according to 21 CFR Part 11 including date, time stamp, user ID
- Integrated workflow for approval and review of reports before publishing
- pH-change support according USP-Method A and B
- Easy XML, PDF, Excel ex-/import for LIMS communication
- Seminal check of the photometer according EP

## Spectrophotometer Options for ERWEKA UV-Vis Systems



|                        | Shimadzu UV-1800               | Agilent 8454                                | Analytik Jena Specord 210 plus |
|------------------------|--------------------------------|---|--------------------------------|
| Range                  | 190-1100 nm                    | 190-1100 nm                                 | 190-1100 nm                    |
| Bandwidth              | 1 nm                           | 1 nm  | 1.4 nm                         |
| Type                   | Dual beam scanning             | DAD   | Dual beam scanning             |
| Connection             | USB                            | LAN   | RS232                          |
| Special                | Stand-alone operation possible | Typical scantime for full spectra:<br>1.5 s | Up to 16 channels              |
| Height x Width x Depth | 270 x 450 x 490 mm             | 185 x 344 x 560 mm                          | 590 x 260 x 690 mm             |
| Weight                 | 15 kg                          | 16,5 kg                                     | -                              |