

RoboDis II Dissolution System

Fully automated dissolution system



The RoboDis II is a 100% USP/EP compliant dissolution system for fully automated dissolution testing of up to 10 batches with USP method 1 (basket) or 2 (paddle).

The high-performance system is managed via the 21 CFR Part 11 compliant Disso.Net software. The software controls all functions including the precise robot arm movement as well as all analytical devices including data processing.

Integrated system suitability tests (SST) ensure reliability and easy control. Due to a parallel sampling approach, very short cycle times for measuring profiles can be realised.

RoboDis II Highlights:

- Fully automated dissolution testing for 10, 20 or 40 batches
- USP method 1 and 2 – basket and paddle
- 100% USP/EP/JP compliant
- pH change in accordance with USP method A (half change) and USP method B (full change)
- pH measuring in each vessel
- Parallel sampling approach
- Handling of Japanese sinkers
- Handling of up to 6 different media (concentrates and/or ready prepared) independently controlled by load cell
- Vacuum degassing of the pre-heated dissolution media in accordance with USP
- Filters precisely fitted by robot hand
- Filtration with flat membrane filters ($\geq 0,22 \mu\text{m}$) supported
- Several analytical methods supported
- Support of several photometers and HPLC-systems
- Sampling time points independent of HPLC runtime
- Integrated system suitability tests (SST) for filling procedure, analytical method, system cleaning and test parameters (e.g. rotation speed, temperature)
- Video monitoring in time-lapse mode with overlaid real time dissolution curve
- Flexible bidirectional connection to various IT systems, LIMS integrated
- 24/7 dissolution testing and documentation with USB 3.0 cameras and LED light bar for illuminating water bath
- User friendly Disso.net software 21 CFR Part 11 compliant Microsoft Windows based, according GAMP 5

Analytical Methods:

- Fraction collection
- HPLC - online connection
- Buffered HPLC – online connection
- UV/VIS - online connection with flow-through cells
- Combination of all of the above
- Combined HPLC and UV/VIS online connection

RoboDis II Dissolution System

Tablet / Basket Storage

- Handling of 10 (optional up to 40) batches per robot start
- Containers/baskets easily accessible at cabinet door
- No negative influences by temperature or humidity
- Handling of tablets, granulates, pellets
- Handling of USP Japanese sinkers supported



40 Batch Sample Holder



40 Batch Filter Holder

Medium Preparation and Supply

- Mobile tank for 120 litre media with optional stirrer
- Up to 6 (SUPAC) different media, media concentrates per start supported
- Preheating and vacuum degassing in accordance with USP
- Filling with precise piston pump, gravimetric controlled
- Parallel preparation of the next media during run
- Handling of foaming media supported

Tablet Handling (Paddle)

- Tablet transfer and parallel tablet drop by robot hand.
- Handling of Japanese sinkers
- High accuracy and reliability
- Pellets and granulates can be handled

Tablet Handling (Basket)

- Basket mounted by robot hand
- Handling in accordance with USP/EP and FDA Mechanical Calibration
- Used baskets are dropped into a container



Automatic media preparator



Up to six different calibration standards

Sampling System Basic

- USP compliant sampling station with 1 μm or 10 μm Poro-plast inline filters
- Temperature measuring in each vessel
- Parallel sampling with valve-free ceramic piston pump PVP
- Closed loop system, no withdrawal of sample

Sampling System Advanced

- USP compliant sampling station with 1 μm or 10 μm Poro-plast inline filters (pre filtration)
- Second filtration with 0.22 μm , 0.45 μm membrane filters with automatic filter changer AFC 825



Filling Hand



Handling of Japanese sinkers, parallel tablet drop

pH change

- pH change in accordance with USP method A (half change) and USP method B (full change)
- Handling of the pH sensor by robot arm
- Automatic measuring of the pH value in one or each vessel
- Documentation of all data obtained including calibration of the pH meter

Automatic Cleaning

- Parallel cleaning performed automatically
- Number of cleaning steps can be chosen
- Result of the cleaning process is checked (SST)
- Contaminated media can be separated
- Integrated water stop



Vessel cleaning



pH change in accordance with USP method A (half change)

Video Recording in Time-Lapse Mode

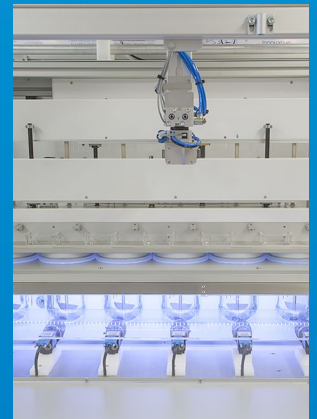
- Video recording of the dissolution process in time-lapse mode
- Up to 6 cameras supported
- Overlapping real-time dissolution curve
- Support for formulation and dissolution method development
- USB 3.0 cameras with USB 3.0 Hub - connect only one cable
- Updated low-light capabilities

Real 24/7 Testing

- LED light bar illuminates water bath and allows use of new video capturing capabilities without the need of external lights
- Energy efficient
- Perfect brightness for recording at night without the need to light whole laboratory



Video recording

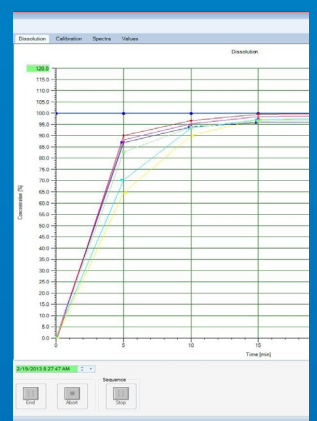


LED light bar for 24/7 video recording

Disso.net Software System Control

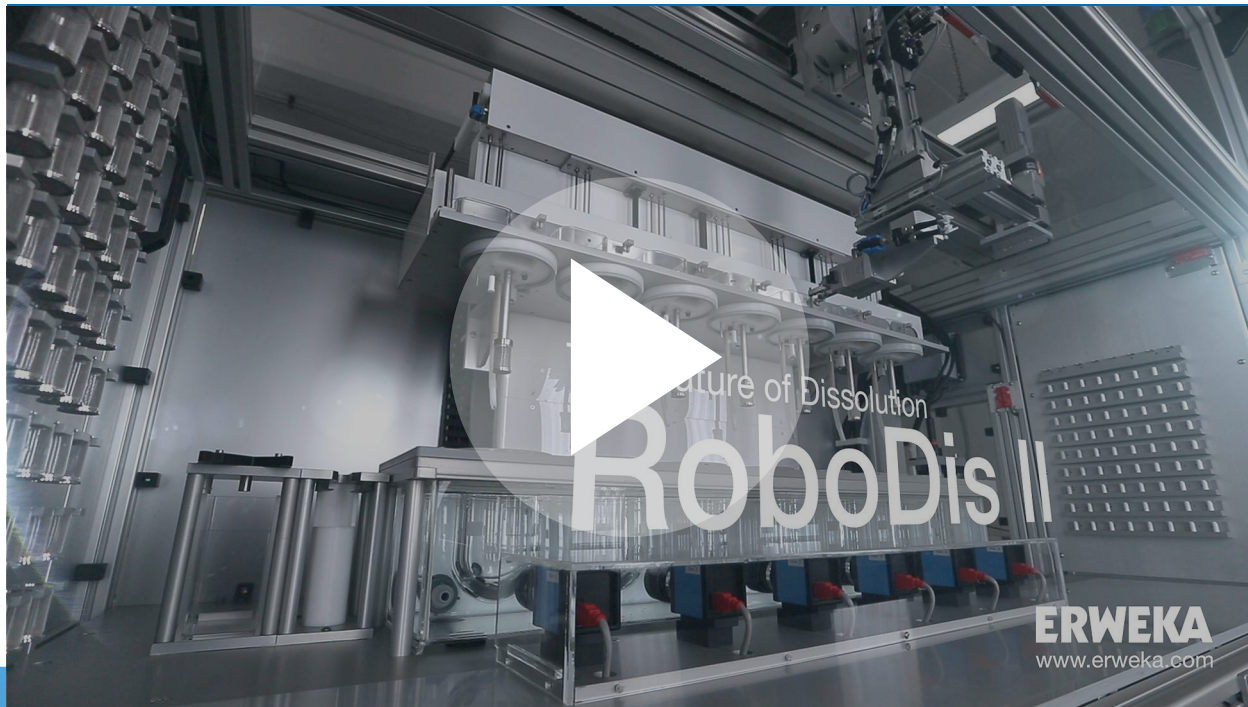
- 21 CFR Part 11 compliant Microsoft Windows based Disso.net software package according GAMP 5
- Interactive communication between RoboDis II and analytical method
- User defined reports via "Crystal Reports"
- Online control of rpm and temperature
- Bidirectional LIMS interface via XML
- Windows XP, Windows 7 and 8 compatible

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|------------------|------------------|------------------|------------|
| 02.2013.13.07.26 | Measuring | UV Spectrum | 4 |
| 02.2013.13.07.51 | Measuring | UV Spectrum | 5 |
| 02.2013.13.08.15 | Measuring | UV Spectrum | 6 |
| 02.2013.13.08.40 | Standard Changer | Set position | 1 |
| 02.2013.13.08.40 | Standard Changer | pump | 1 10 ml |
| 02.2013.13.08.55 | Measuring | UV ControlStanda | 100 % Stan |
| 02.2013.13.09.20 | Cyclic | PointOffTime | 18 30 min |
| 02.2013.13.18.43 | Tubes | down | |
| 02.2013.13.18.59 | Pump | started | 45.5 s |
| 02.2013.13.19.44 | Sync | Sample | |
| 02.2013.13.19.44 | Pump | continue running | 27.5 s |
| 02.2013.13.20.11 | Pump | stopped | |
| 02.2013.13.20.13 | Speed | min | 1 50 1/min |
| 02.2013.13.20.14 | Speed | max | 1 50 1/min |
| 02.2013.13.20.14 | Temperature | Bath min | 1 37.2 °C |
| 02.2013.13.20.14 | Temperature | Bath max | 1 37.4 °C |
| 02.2013.13.20.19 | Temperature | Vessel | 1 37.2 °C |
| 02.2013.13.20.19 | Temperature | Vessel | 2 37.2 °C |
| 02.2013.13.20.19 | Temperature | Vessel | 3 37.2 °C |
| 02.2013.13.20.19 | Temperature | Vessel | 4 37.2 °C |
| 02.2013.13.20.19 | Temperature | Vessel | 5 37.2 °C |
| 02.2013.13.20.19 | Temperature | Vessel | 6 37.2 °C |
| 02.2013.13.20.19 | Tubes | up | |
| 02.2013.13.20.20 | Measuring | UV Reference | |
| 02.2013.13.20.48 | Measuring | UV Spectrum | 1 |
| 02.2013.13.21.17 | Measuring | UV Spectrum | 2 |
| 02.2013.13.21.41 | Measuring | UV Spectrum | 3 |
| 02.2013.13.22.06 | Measuring | UV Spectrum | 4 |
| 02.2013.13.22.31 | Measuring | UV Spectrum | 5 |
| 02.2013.13.22.56 | Measuring | UV Spectrum | 6 |
| 02.2013.13.23.20 | Standard Changer | Set position | 1 |
| 02.2013.13.23.20 | Standard Changer | pump | 1 10 ml |
| 02.2013.13.23.38 | Measuring | UV ControlStanda | 100 % Stan |
| 02.2013.13.24.01 | Standard Changer | Clean | |



The Disso.net software controls the system and transfers data

See RoboDis II in action!



Visit www.erweka.com for our latest video and more information about the RoboDis II.

At www.erweka.com you will find:



- RoboDis II video - see it in action!
- Detailed pictures of RoboDis II
- Downloads



Technical specifications for the products described are stated without warranty and subject to change at any time.
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