

# Dissolution System RoboDis II

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 up to 10 batches
- USP method 1 and 2 – basket and paddle
- 100% USP/EP/JP compliant
- pH change in accordance with USP method A (half 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 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 integrated

## 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

# Dissolution System RoboDis II

## Tablet / Basket Storage

- Handling of up to 10 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

## 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

## Sampling System Basic

- USP compliant sampling station with 1 µm or 10 µm Pore-plast inline filters
- Temperature measuring in each vessel
- Parallel sampling with peristaltic pump IPC 8
- Closed loop system, no withdrawal of sample



Easy placement of tablet containers in cabinet door



Precise basket mounting



Automatic media preparation



Up to six different calibration standards



Filling hand



Handling of Japanese sinkers, parallel tablet drop

### Sampling System Advanced

- USP compliant sampling station with 1 µm or 10 µm Poro-plast inline filters (pre filtration)
- Second filtration with 0.22µm, 0.45µm membrane filters with automatic filter changer AFC 825
- Valve-free ceramic piston pump PVP 820

### pH change

- pH change in accordance with method A (half 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



UV/VIS online connection



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

### 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

### 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



Vessel cleaning

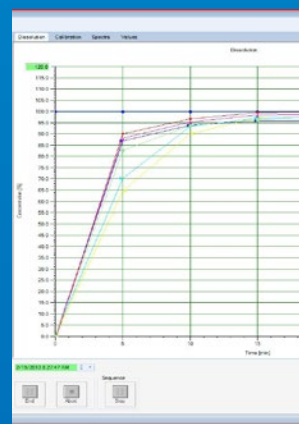


Video recording

### System Control

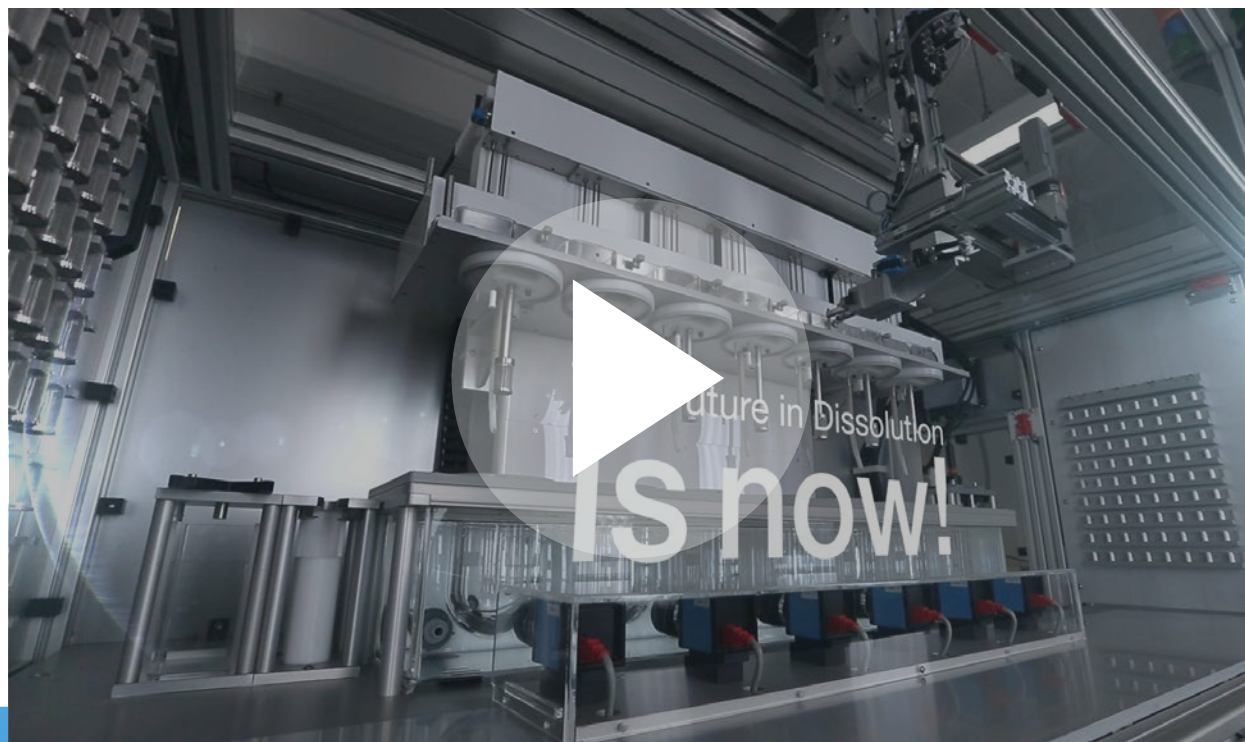
- 21 CFR Part 11 compliant Microsoft Windows based Disso. Net software package
- Interactive communication between RoboDis II and analytical method
- User defined reports via "Crystal Reports"
- Online control of rpm and temperature
- Bidirectional LIMS interface via XML
- Windows XP, Windows 7 and 8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

02.2013.13.07.26	Measuring	UV Spectrum	4
02.2013.13.07.57	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 Control/Stand	100 % Star_2
02.2013.13.09.20	Cycle	PumpOffTime	16 20 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 27.2 °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	
02.2013.13.20.45	Measuring	UV Spectrum	1
02.2013.13.21.17	Measuring	UV Spectrum	2
02.2013.13.21.47	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
02.2013.13.23.36	Measuring	UV Control/Stand	100 % Star_2
02.2013.13.24.07	Standard Changer	Close	



The Disso.net software controls the system and transfers data

# See RoboDis II in action!



Visit [www.robodis.com](http://www.robodis.com) for our latest video and more information about the RoboDis II.

At [www.RoboDis.com](http://www.RoboDis.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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