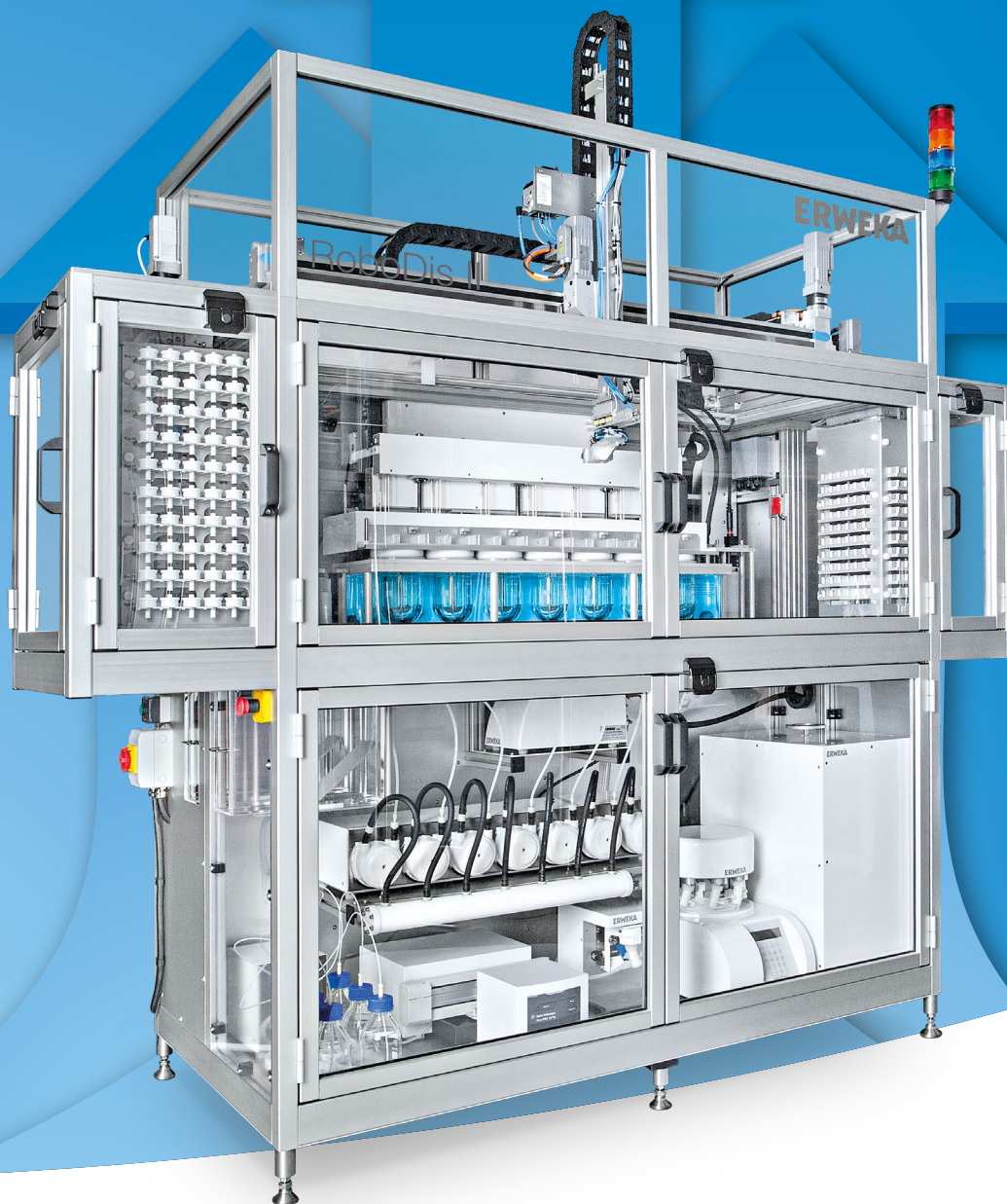


# The Productivity Booster RoboDis II

Fully automated dissolution system



**ERWEKA**

## Dissolution Steps



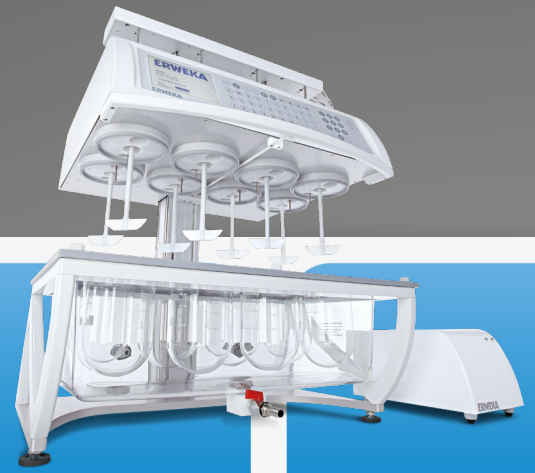
Set-up

1.



Media preparation & filling

2.



Tablet drop, stirring of baskets or paddles

3.

Automated Sampling & Filtration

4.

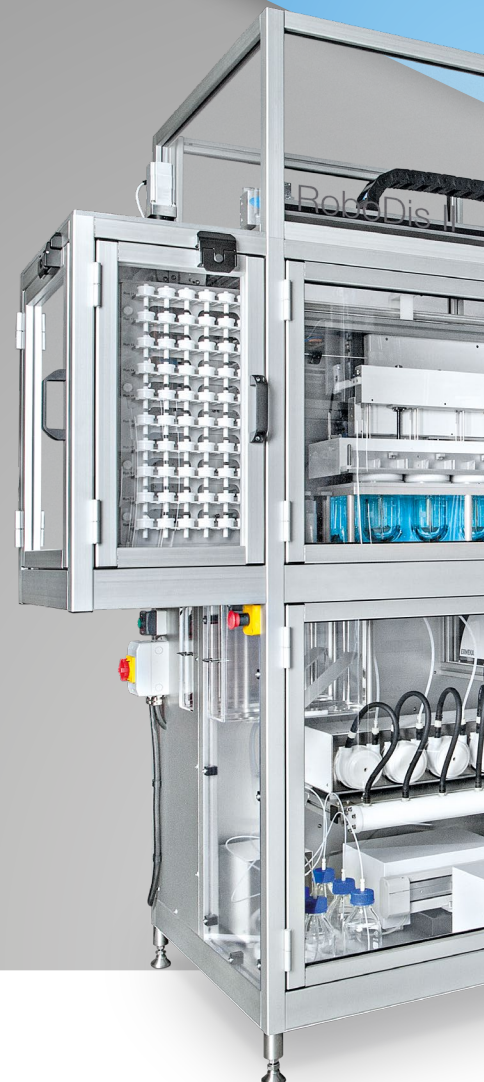
## Your challenge

Generate reliable test results within the shortest possible time

As a long-standing partner of the pharmaceutical industry we are fully aware of the challenges inherent in the dissolution test procedure. Test results have to be reliable, reproducible and documented fully and comprehensively. At the same time laboratory staff is faced with enormous time constraints, in view of ever shorter production cycles and the need to release batches in increasingly shorter time.

Although traditional semi-automatic dissolution testers provide some improvement for these test procedures, demands on time and human resources are still enormous. In addition, the human influence on the process is high – which may result in time-consuming and costly errors.

***Our vision:*** A fully automated dissolution test system designed to supply highly reliable results and accelerate the test process several times over.





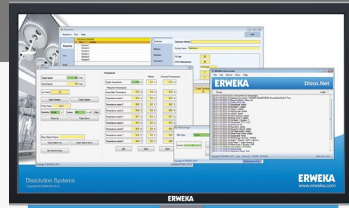
Store sample in glass tubes/  
HPLC vials for analysis

5.



2nd Filtration

6.



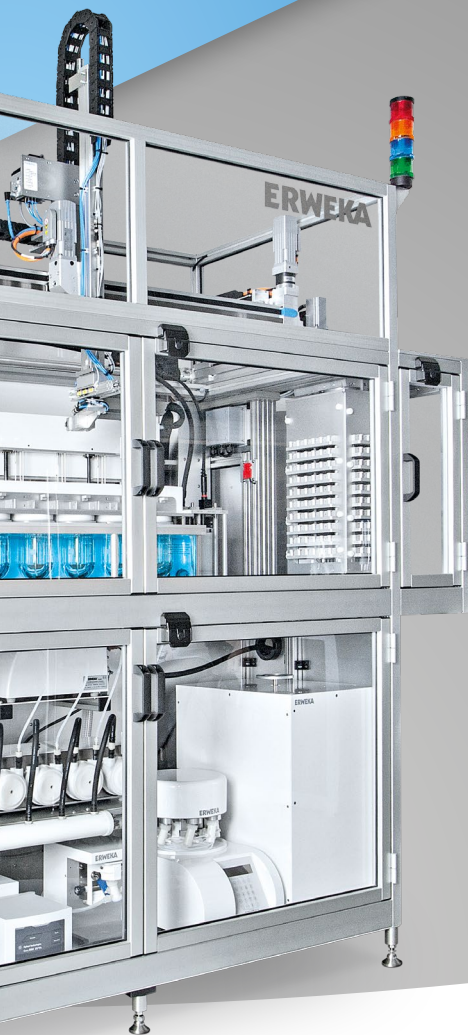
Analysis of samples  
(UV-Vis or HPLC)

7.



Cleaning process

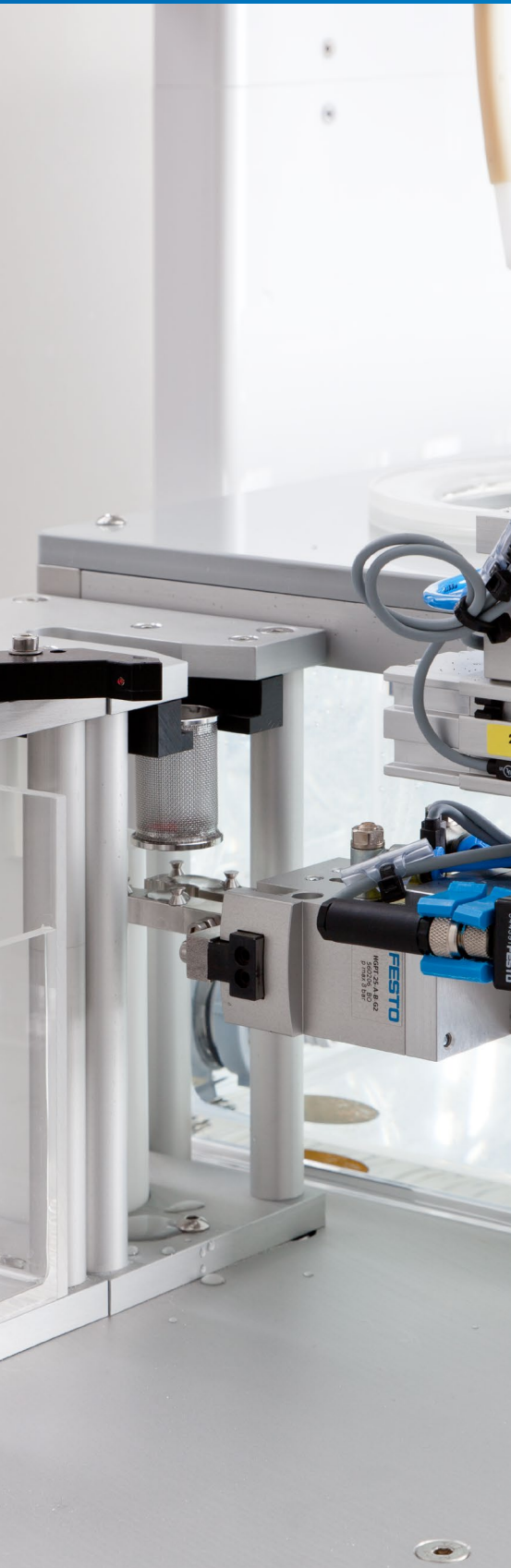
8.



## Who we are

ERWEKA – A visionary and experienced partner for the pharmaceutical industry

Erweka is one of the leading international manufacturers of premium test equipment for development and quality control of pharmaceutical solid dosage forms. For more than 65 years we have supplied our products to major pharmaceutical and life science companies, development and test laboratories and pharmaceutical-technical universities worldwide. Our vast product portfolio ranges from physical testers to dissolution testers in accordance with USP 1, 2, 3, 4, 5, 6 and 7, and our experience in this sector is second to none. We are committed to a philosophy of continuous innovation, which spurs us on to ever new achievements in the development of our products – with a continuous focus on automation.



# Our innovation - RoboDis II

RoboDis II – the only parallel-working, fully automated dissolution tester on the market

RoboDis II is the only parallel-working, fully automated dissolution test system currently on the market. All stages of the dissolution processes are computer-controlled and therefore carried out entirely without user intervention. The key element of the fully automatic system is the Disso.NET software developed by ERWEKA, which handles all system functions, including the precise movement of the robot arm, control of the analytic devices, data processing and full documentation.

In the standard configuration, RoboDis II tests up to 10 batches in accordance with USP methods 1 (Basket) or 2 (Paddle). The parallel sampling approach enables very short cycle times for recording of detailed drug release profiles to be selected by the user. Integrated System Suitability Tests (SST) and video monitoring ensure a high degree of reliability. Like all ERWEKA products, RoboDis II is fully USP/EP/JP compliant.

RoboDis II is therefore the answer to all challenges of dissolution testing:



**Highly accurate and reliable testing:** Improves drug safety.



**Accelerated testing:** Avoids bottlenecks in the batch release process..



**Automatic execution of repetitive tasks:** Reduces operator fatigue, enabling operators to focus on higher-value tasks. .



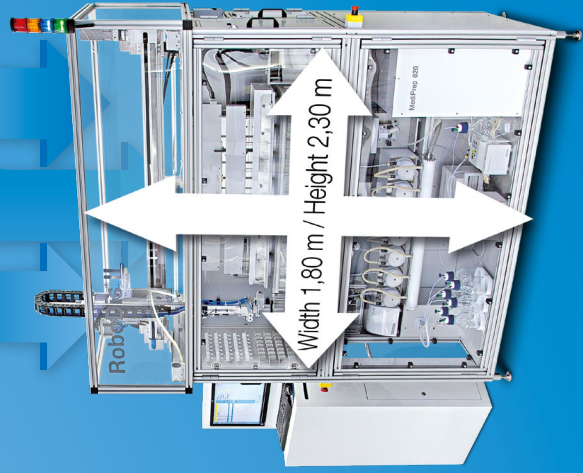
**Long-term cost reduction:** RoboDis II will pay back for itself within a short term. .

# Small Footprint, Great Results

Three complete semi-automatic dissolution testers including media preparation and vessel cleaning - this is the amount of floor space you can save with a RoboDis II 10-batch system, which has a footprint of no more than 2x1m.



Laboratory space required to achieve the productivity of a single RoboDis II 10-batch system with conventional semi-automatic systems: 10+ m



Width 1.80 m/Height 2.30 m

# A flexible specialist

## RoboDis II in R&D

### Multiple dosage forms

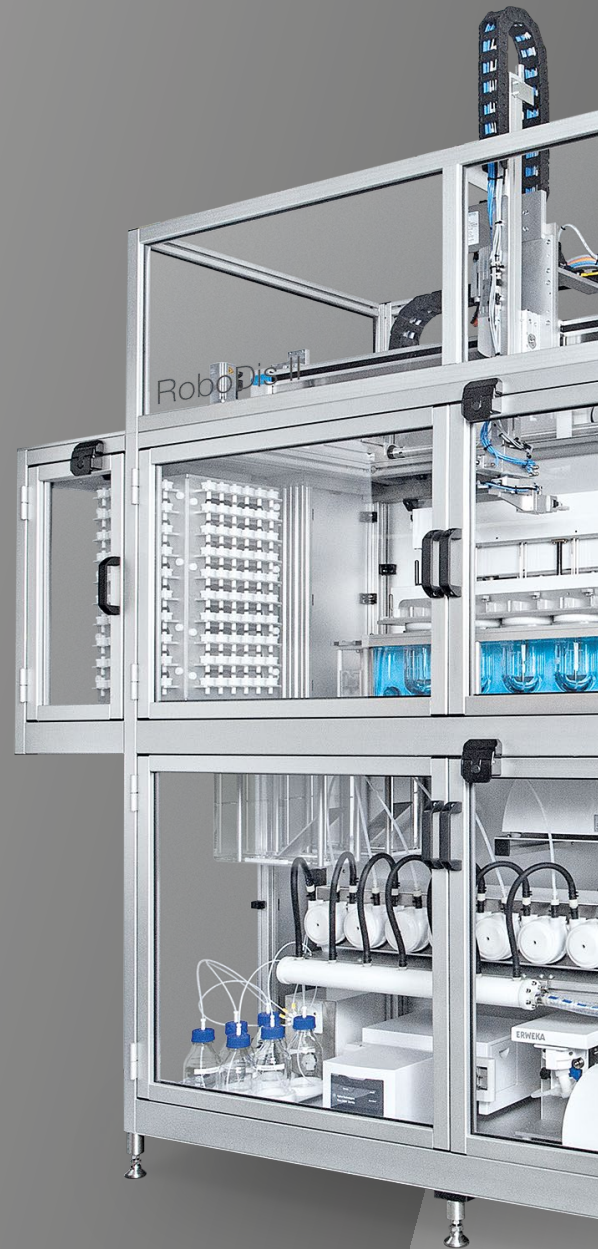
RoboDis II is capable of handling pharmaceuticals in a variety of different dosage forms. Regardless of whether your laboratory handles tablets, granulates or powders - RoboDis II is the ideal, highly flexible and full automated dissolution system for your requirements. Even sinkers up to 34 mm are supported.

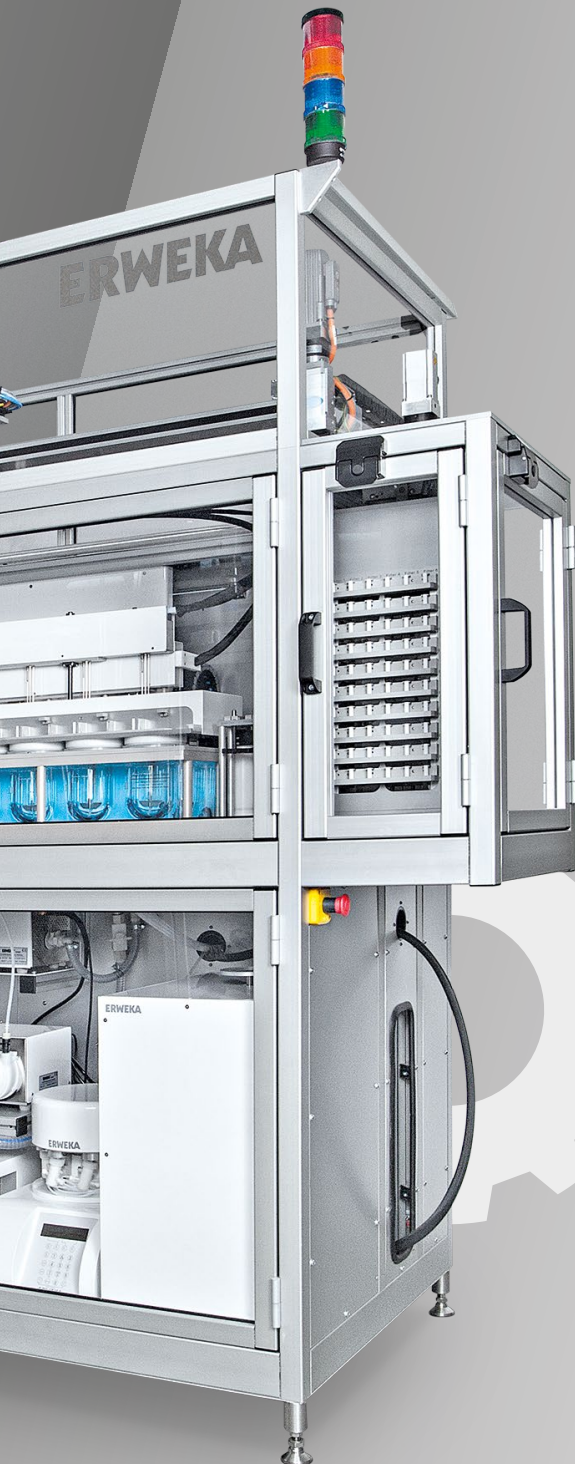
### Flexible filtering options

There are virtually no limits for filtering with RoboDis II – the system supports Poroplast inline filters, membrane filters and even double filtration.

### pH change: half change and optional full change

RoboDis II provides fully automatic pH change (half-change and optional full change) - simply configure your method with our powerful Disso.NET software and start the test - RoboDis II will handle all further steps.





### Various options for connecting to analytic devices

RobDis II features fully automated, integrated online analytics, offering a broad spectrum of capabilities ranging from simple spectrophotography with a UV/Vis device to complex HPLC chromatography, or a combination of both.

### Six reference standards

Central to the development were flexible reference standards for rapid test-out of a variety of different formulations – no problem for RoboDis II and its integrated media preparation features.



# Boost Your Productivity

## RoboDis II for quality control

### Productivity to suit your requirements with 10, 20 or 40 batches

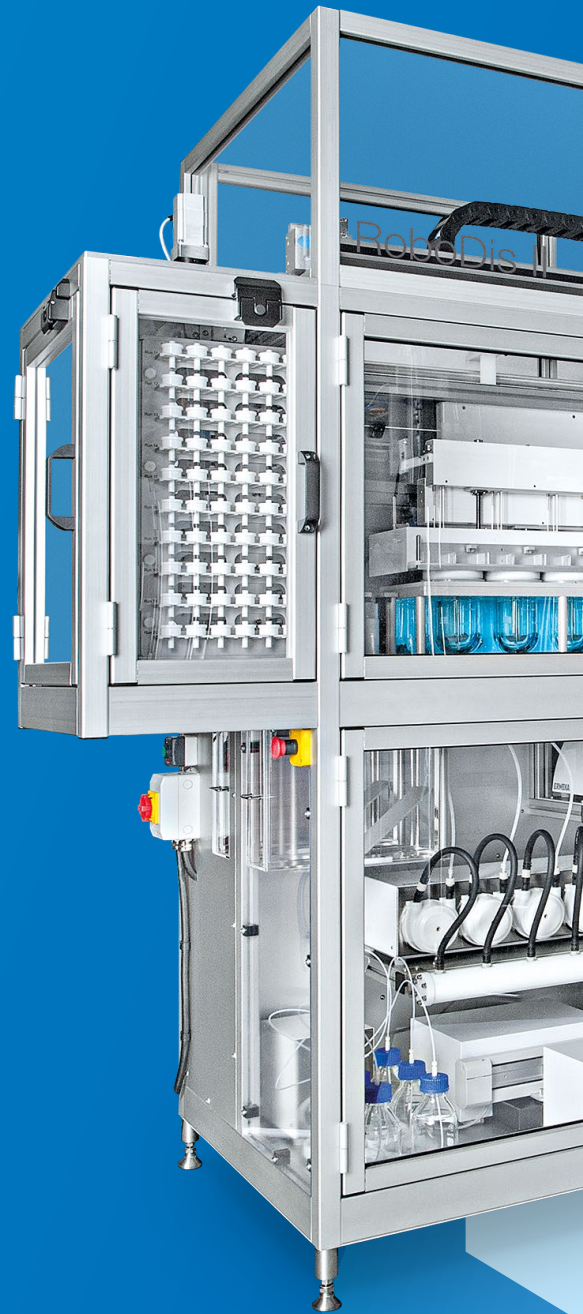
RoboDis II's productivity can be conveniently scheduled well in advance, independent of staff working hours. Equipped with 40 batches, RoboDis II can run, for example through an entire weekend, and have the results ready for evaluation by your laboratory staff on the following weekday. Video recording enables laboratory staff to go back to any desired point of the test for visual inspection and verification.

### High sample volumes - 40 batches

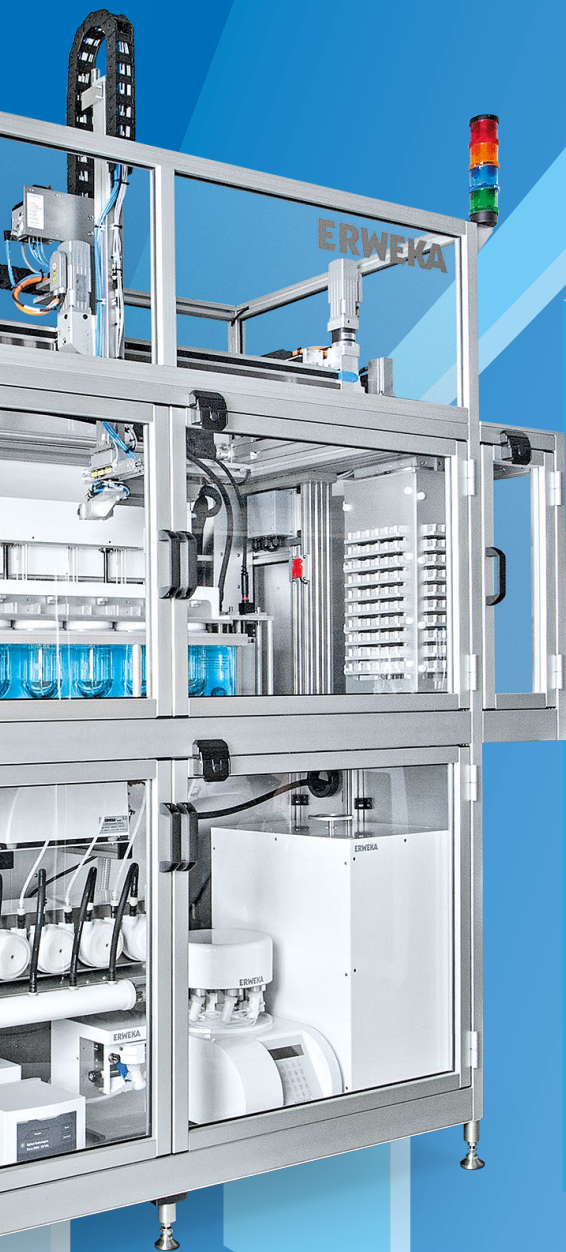
Testing non-stop – there is nothing that RoboDis II can do better. The 40-batch option enables a rate of testing commonly achieved only by employing multiple semi-automatic systems, requiring much more laboratory space and more laboratory staff.

### Parallel action

RoboDis II is a parallel-acting system - the medium for the subsequent test is prepared even while the current test run is in progress. In addition, extremely short cycles can be achieved, e.g. by sampling after only 5 minutes. Needless to say all this happens fully automatically.







### Robotic precision & fault monitoring


Each step of the RoboDis II test procedure is fully automated and is verified automatically by the software – this means that RoboDis II always performs test procedures in exactly the same way, thereby eliminating the human factor. RoboDis II offers maximum reliability and frees your laboratory staff for more challenging tasks - such as the analysis of the data obtained.

### Space-saving footprint

Achieving the productivity of a RoboDis II system with other, semi-automatic systems would require four times more space (for a 10-batch system).



## RoboDis II features




**Sample magazine for 10, 20 or 40 batches**

In the 40-batch version, RoboDis II enables true 24/7 testing and is capable of handling 40 batches without human intervention.


**A high-precision robot arm**

A Festo pneumatic robot arm takes care of all repetitive tasks within the RoboDis II system: Placement and removal of all sample containers and filters, filling with medium, sample withdrawal, basket (dis)mounting and cleaning of the vessels.




**Integrated controller with Disso.NET**

Control of all RoboDis II functions is provided by an industrial controller with integrated Disso.NET software through the local RoboDis II network. All integrated devices, such as analytic devices, video cameras or sample magazines are linked through a high-speed Gigabit Ethernet network.



**pH changes**

Optional pH measurement permits pH changes according to USP Method A (half change) and Method B (full change).



### 40-batch filter magazine

The 40-batch option with revolving magazines comes with a 40-batch filter holder. These Poroplast filters are mounted and dismantled fully automatically for each test by the robot arm.



### Built-in media preparation

The built-in media preparation feature fully automatically prepares the medium for the testing procedures. Media preparation is configured through the Disso.NET software, with RoboDis II taking care of all other steps.



### Seven test vessels

Seven USP-compliant test vessels in the RoboDis II system support testing in R&E and in quality control. In quality control, for example, six samples may be compared to a reference sample. Alternatively, seven different samples can be tested in parallel for Research & Development.



### Precise piston pump

The highly precise piston pump with ceramic heads is virtually maintenance free and ideally suited to the high sample volumes handled by RoboDis II.



### Online UV-Vis analysis or HPLC

RoboDis II supports integrated online UV-Vis or HPLC analytic devices. Samples are withdrawn fully automatically and transferred to the analytics devices.



### Use of paddles and baskets

RoboDis II supports the use of both paddles (USP 2) and baskets (USP 1), both of which can be exchanged by the user (guided with Disso.NET).



### Japanes sinkers and sinkers up to 34 mm

RoboDis II supports the use of sinkers to max. size of 34 mm. Dropping and removal of sinkers take place fully automatically with the sinker tool provided.





RoboDis II performs routine tasks more precisely than any human operator – but without a human operator all its powerful fully automatic features would be worth nothing. It is the human operator who defines the test methods, checks results for plausibility and interprets the data obtained. To enable him or her to focus on these tasks, we have equipped RoboDis II with a number of safety features.

**Not smarter, but more reliable**

#### System Suitability Tests (SST)

In each individual process step, RoboDis II self-checks by means of integrated System Suitability Tests (SSTs). Several built-in light barriers validate the steps performed by RoboDis II, thus preventing false starts.

#### Complete documentation

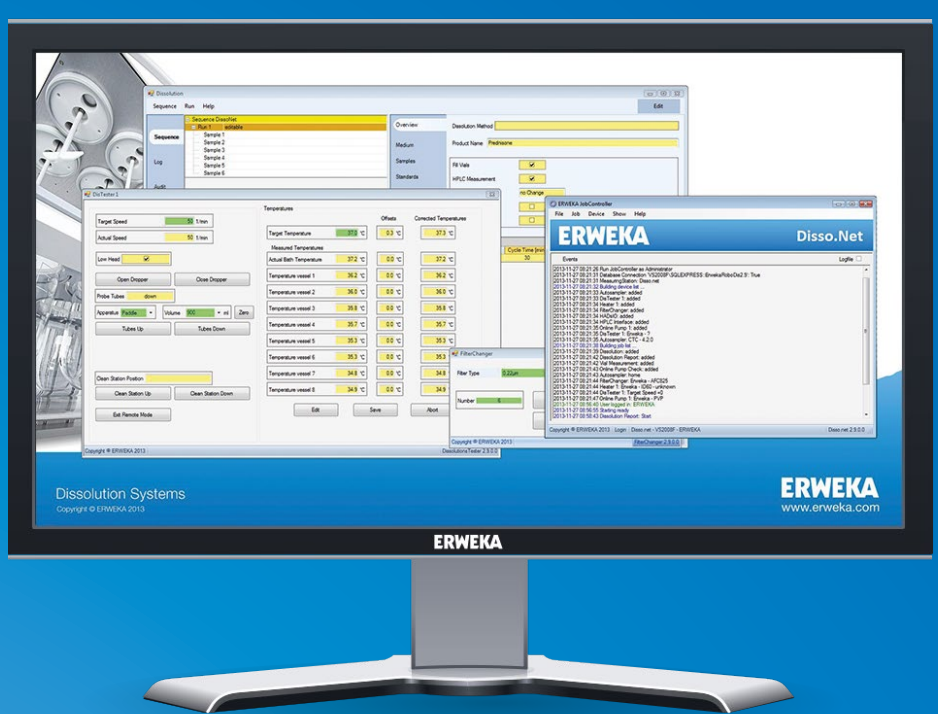
Each step of the test is logged in accordance with the industrial standard 21 CFR Part 11. This will enable you to check, for example, whether RoboDis II actually did test all 40 batches completely over the weekend

#### High-quality system components

RoboDis II is built with tried-and-tested, reliable system components, amongst them, e.g., ERWEKA's maintenance-free PVP pump and the robot arm made by the internationally renowned pneumatics manufacturer Festo. The use of premium components guarantees maximum precision and lowest downtimes.

#### Video recording

RoboDis II optionally records the entire dissolution process with six integrated video cameras. This allows validating the entire test upon completion, or overlaying the dissolution curve on a time-lapse video recording. Thanks to the LED light strip the water bath can be illuminated at night, allowing 24 hour video recording without the need for external lighting.



# Disso.NET

The key element in the RoboDis II test system

RoboDis II is controlled fully automatically by its integral controller equipped with the Disso.NET software. Designed by ERWEKA specially for the purpose, the Disso.NET-Software constitutes the key element of the RoboDis II system:

A user-friendly editor enables the required dissolution test methods to be defined and started. Disso.NET then manages all steps of the dissolution process from media preparation through to analysis. The software also controls the precise movement of the robot arm and the connected analytical devices. Disso.NET logs all test results and times, and automatically creates an audit trail. Upon completion of the test, the software generates extensive reports and enables export of all test results. In addition, the software controls the System Suitability Tests and the video recording functions.

## Highlights

- Comprehensive management of users, methods and reports
- Multi-user support including allocation of different user roles (user, senior operator, administrator)
- Awarding of different user rights to users and administrators
- Complete audit trail in accordance with 21 CFR Part 11 including date, time stamp and user ID
- MS SQL database - Reliable backup and storage features
- Extended reporting features in various formats (xml, xls, pdf, pdf-A) including export function
- Connectivity to LIMS possible

## Highlights

-  Complete audit trail according to 21 CFR Part 11
-  Video support
-  Support of USP methods 1 & 2
-  MS SQL database
-  Advanced report generation



# Premium Service for a premium product

Our aim is to serve you right from the point when you express an interest in purchasing our RoboDIS II system: Together we will analyse your real requirements, select the fitting components and then build the system exactly to your specifications. This means that every RoboDis II is a purpose-built, fully automated system.

Following installation of the system, we will develop a customized service strategy geared towards our four service objectives: maintaining durability, ensuring measuring accuracy, providing highly responsive customer support, and, above all, ensuring that users are optimally trained in the use of the system. Based on the jointly developed service schedule, service costs will be predictable and consistent.

RoboDis II is a premium product for which we provide premium preventive maintenance service. All service requests will be given top priority by us.

## Maintaining durability

- Installation by two RoboDis II specialists covering a period of one week
- Preventive Maintenance by RoboDis II specialists at 6-monthly intervals
- Inspection by RoboDis II specialists at 6-month intervals

## Ensuring measuring accuracy

- Installation Qualification (IQ)
- Operation Qualification (OQ)
- Automation Verification Test for dissolution systems (AVT)

## Highly responsive support

- 24 h RoboDis response hotline
- Your direct service contact
- Immediate repair service





## References

If you would like to talk to RoboDIS II users to find out how the system is integrated into their laboratory environment, simply call us: We will be happy to provide you with a contact!



Please feel free to contact us:

+49 6104 6903-0

Our ERWEKA service commitment:

- Fast response times
- Speedy expert service
- Service bases all over the world
- Unique manufacturer know-how
- ERWEKA-certified service staff
- Full availability of spare parts
- Customized service strategy



**12 months return policy:** We are confident that our system will run satisfactorily and will guarantee this with a 12-months return policy from system installation.

# The Facts

## Paddle, baskets and sinkers

- Tablet holders / baskets
- Handling of 10 (optionally up to 40) batches per robot start
- Vessels / baskets easily accessible in the cabinet door
- No negative influence of temperature or humidity
- Handling of tablets, granulate and pellets
- Supports handling of sinkers measuring up to 34mm



40 batches tablet holder

## Media & media preparation

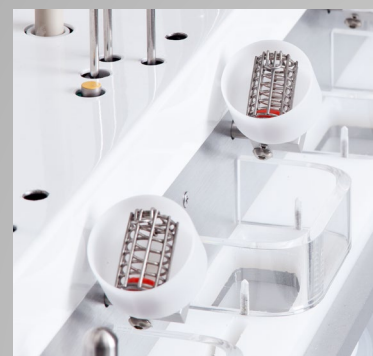
- Automatic media preparation and supply
- Mobile tank for 120 litres of medium with optional stirrer
- Supports up to 6 (SUPAC) different media or media concentrates per start
- Preheating and vacuum degassing in accordance with USP guidelines
- Dosing with gravimetrically controlled precise piston pump
- Parallel preparation of the next medium during the dissolution test run
- Supports handling of foaming media



Up to 6 different calibration standards

## Tablet handling (with paddles)

- Parallel tablet drop
- Handling of sinkers up to 34 mm, handling of japanese sinkers
- High accuracy and reliability of process steps
- Supports pellets and granulates

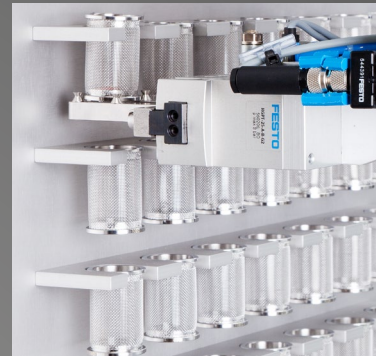


Handling of japanese sinkers, parallel tablet drop



## Tablet handling (baskets)

- Mounting & dismounting of baskets by robot arm
- Used baskets are automatically dropped in cleaning container



Automatic basket handling

## Basic sampling system

- USP-compliant sampling station with Poroplast inline filters
- Temperature measurement in each vessel
- Parallel sampling with valve-free ceramic piston pump PVP, virtually maintenance-free
- Closed-loop sampling system



Poroplast filter handling

## Advanced sampling system

- USP-compliant sampling station with Poroplast inline filters (pre-filtering)
- Additional filtration with membrane filters with AFC 825 filter changer

# The Facts

## pH change

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



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 could be checked (SST)
- Contaminated media can be separated
- Integrated water stop



Vessel cleaning

## Video recording

- Video recording of dissolution process in time-lapse mode
- Supports connection of light-sensitive cameras
- Overlaying of dissolution curve
- Support for formulation and dissolution method development
- Gigabit Ethernet camera connection - high bandwidth and easy integration into RoboDis II local network
- LED light strip allows video recording at night without external light



Video recording

## 24/7 testing

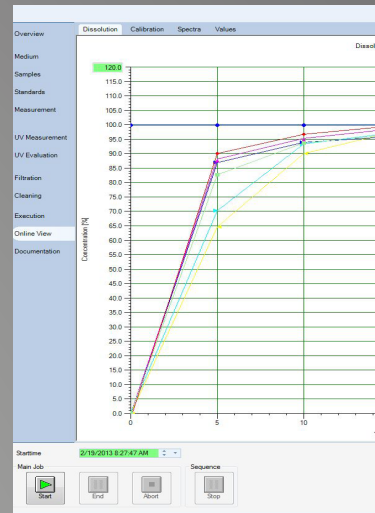
- LED light strip illuminates water bath and allows use of new video capturing capabilities without the need for external lights
- Energy efficient
- Perfect brightness for recording at night without the need to illuminate the complete lab



LED light strip for 24/7 video recording

## System control with Disso.NET software

- 21 CFR Part 11 compliant Disso.NET software suite according to 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



Dissolution curve



## Contact

For further information on our RoboDis II system, please visit our website, where you will find videos, further images and this brochure for download.



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