AT MD
Fully Automated Dissolution System

Fully automated from media preparation to data reporting
Basket and paddle methods as well as sinkers including Japanese sinkers
Up to 8 unattended batches
Supported by SOTAX Global Service Network

Automated Dissolution Testing
With more than 30 years of experience in automating dissolution and hundreds of installed systems all over the world, SOTAX continues to set the benchmark for fully automated dissolution testing. Our highly reliable and proven dissolution systems are developed in close partnership with internationally leading pharmaceutical companies and fully comply with regulatory requirements.

Why Automate Dissolution Testing?

Improve Data Reliability

With the introduction of automation in the lab, you can significantly improve the quality of your data. Each dissolution test is performed the same way, every time, for more precise datasets. Every step is recorded in a secure database reducing instances of data entry errors. Test results are no longer operator dependent.

Increase Productivity

Automated dissolution improves the productivity of a lab creating "walk away time" for operators, allowing more time for "mission critical" activities (i.e. method development, process validation, data checking and verification). Reducing cycle times and completing more work with existing resources.

Shorten Cycle Times

The strategic implementation of laboratory automation is helping many companies to remain competitive. By placing automation in both R&D and Quality departments, some companies have created a seamless method transfer process, helping reduce the time-to-market for new products.

Enhance Safety

Automation improves safety by reducing exposure to hazardous solvents and compound materials used in testing. In addition, automation reduces ergonomic stress by eliminating common repetitive tasks, such as sampling and filtering.

Reduce OOS Results

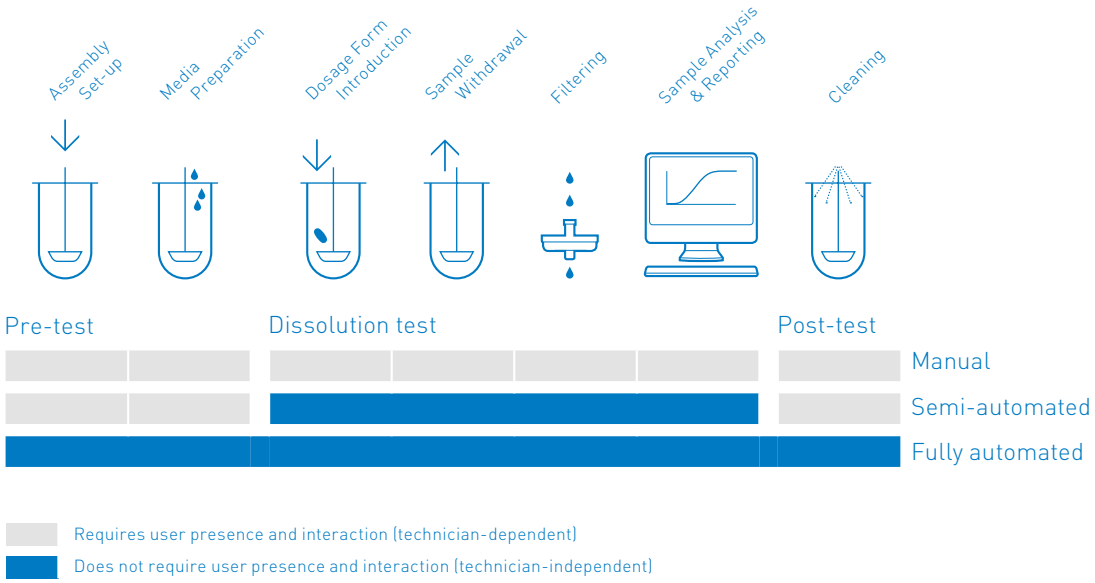
Deficiencies in laboratory investigations are a major source of warning letters in the pharmaceutical industry. Automated dissolution testing reduces the potential for human error and simplifies the investigation process.

Dissolution Automation Levels

Choosing the level of automation that best fits the product and throughput requirements, process steps described in the pharmacopeias, and laboratory standard operating procedures (SOPs), can help to ensure reproducibility and standardization of your dissolution test.

The sequence of individual process steps before (pre-test), during (dissolution test), and after (post-test) the dissolution test include:

Required Steps



Manual steps

When dissolution is performed manually, every single process step before, during, and after the test is executed manually by the user. This is the most technician-dependent way of testing.

Semi-automated steps

Semi automated systems ensure that all the sequential steps done during the dissolution run are reproducibly executed without need for user interaction until the post-run activity.

Fully automated steps

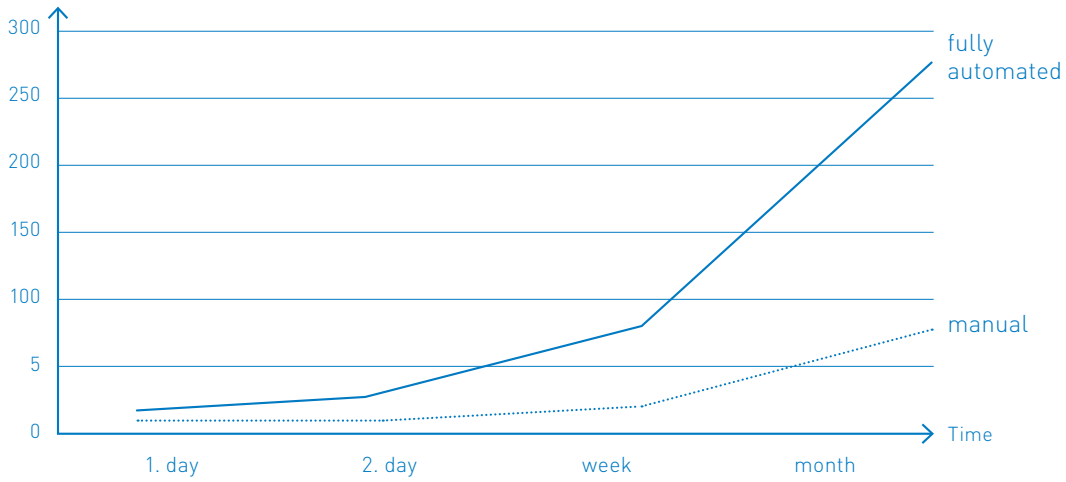
Fully automated systems automate the complete dissolution process – from the preparation through the entire dissolution test including end cleaning, and preparation and execution of a subsequent test of the same or different product. Automating the complete cycle, allows running up to 8 dissolution tests in a row – without user interaction.

The following are the main criteria for choosing the level of automation needed:

- Quantity of test per year
- Duration of dissolution test
- Number of timepoints
- Number of additional process steps / options

The higher the level of automation, the higher the level of reproducibility and throughput.
With higher throughput products, a better ROI for automation is typically realized.
For this reason, many pharmaceutical companies around the world have chosen SOTAX fully automated dissolution platforms and rely on the quality of the AT MD and the AT 70smart to develop their formulations and to release their batches.

Number of tests



→ Simplified Method Transfer
To simplify method automation, transfer, and validation, the design of SOTAX fully automated systems is based on manual instruments and integrates existing peripherals, software, and – more importantly – existing dissolution baths, components, and accessories.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The new AT MD Fully Automated Dissolution System

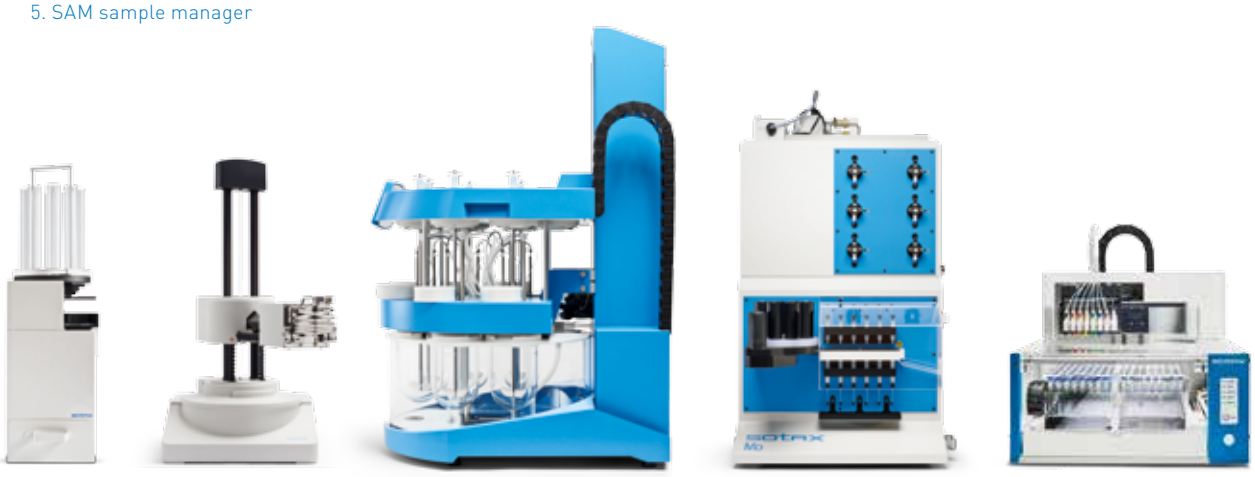
From pre-run to runtime to post-run system cleaning, SOTAX streamlines your workflow through the design of features that guide method development and simplify routine operation.

The AT MD is a fully automated bench-top dissolution system and can handle basket and paddle methods as well as sinkers including Japanese Sinkers. It runs up to 8 unattended batches – from media preparation to data reporting.

The AT MD is driven by the 21 CFR Part 11 compliant MD software. The design of SOTAX dissolution systems is compliant with all harmonized pharmacopeia requirements for paddle and basket methods. From set-up (fixed position vessels and auto-centering) through the complete dissolution test to mechanical calibration (executed with the SOTAX MQD): all requirements are fulfilled.

→ SOTAX AT MD dissolution bath and MD station

→ From left to right:
1. Basket station
2. Robotic arm
3. AT MD dissolution bath
4. MD station
5. SAM sample manager



Components

The SOTAX AT MD fully automated dissolution system consists of the following components:

- Basket station: used for USP 1 test and USP 2 test with sinkers, the basket station holds 8 batches of baskets and handles the used baskets and sinkers after the test.
- Robotic arm: used for USP 1 test and USP 2 test with sinkers, it transports accurately the sinkers and baskets between basket station and AT MD dissolution bath before and after the dissolution test.
- AT MD dissolution bath: used for USP 1 and 2 dissolution test on 6 samples.
- MD station: used to prepare and dispense media into the bath vessels before the dissolution test, introduce the samples, take temperatures, pump and filter samples and standards through six individual channels, and vessel cleaning.
- SAM sample manager: used to collect, store, and protect samples for analysis.

Dissolution Bath Design

The AT MD bath is the core of the AT MD fully automated bench-top dissolution system. The same bath is also available as a standalone manual bath, allowing for simplified throughput scale-up and dissolution method transfer.

Video monitoring is a useful tool for R&D visualization and OOS troubleshooting in QC. The integrated space-saving design of the AT MD offers a protected central space for individual adjustable cameras and an indirect lighting source. The mounting system was designed to assure a controlled focal distance to standardize vessel-to-vessel video and image comparisons. Built-in TCP/IP monitoring allows operators to check progress remotely. Built-in USB, LAN (TCP/IP), RS 232, and Bluetooth interfaces for printer and computer connections open a wide range of connectivity possibilities, including:

- Method transfer via USB flash drive
- Integration of dissolution system operating manuals
- Streamlined Qualification with the SOTAX MQD for mechanical qualification
- Remote access and monitoring
- And more...

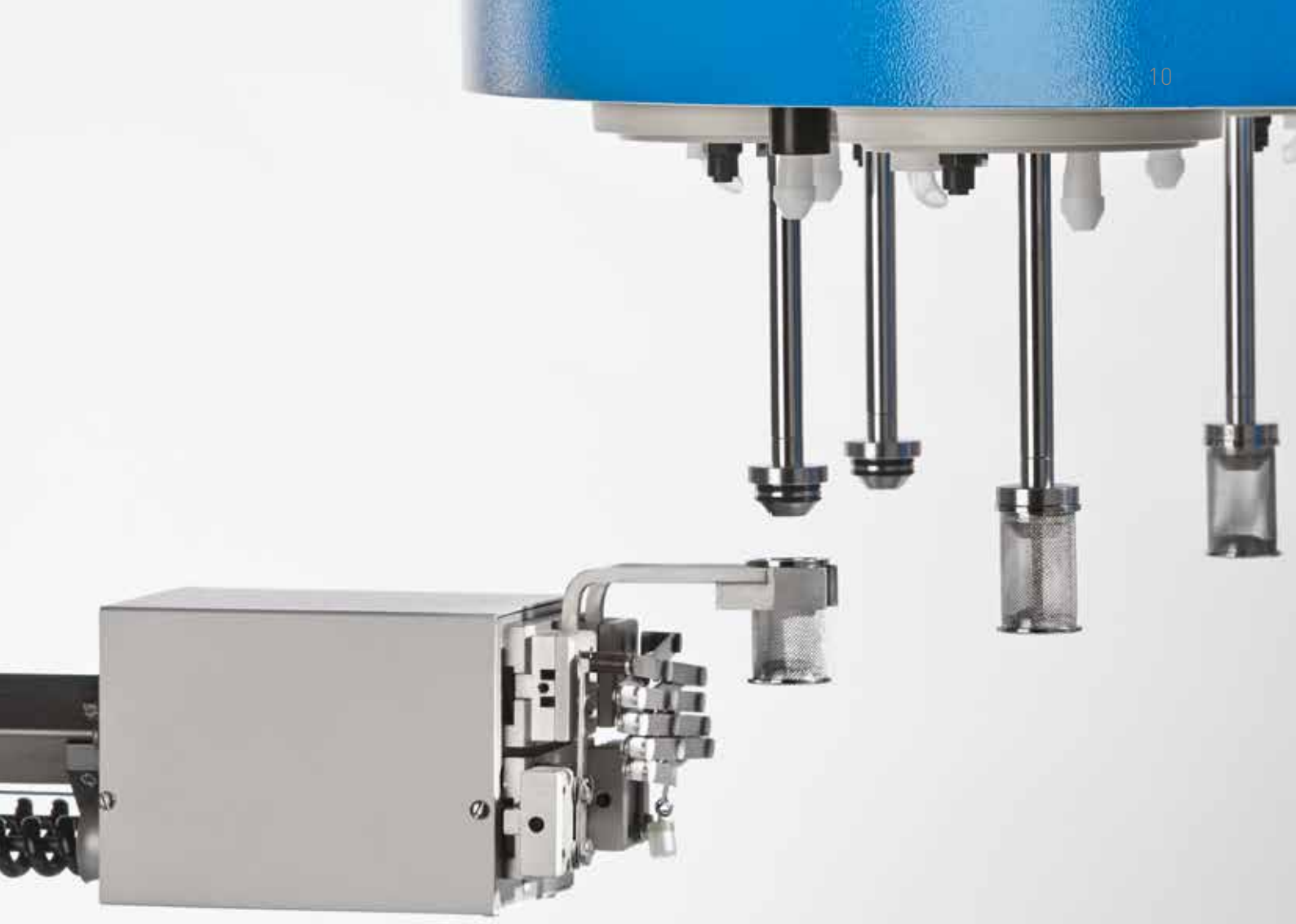
Fully Automated Steps

Media Preparation & Delivery

Up to 5 different media (including concentrates and media with surfactants) per sequence of 8 tests can be automatically heated, degassed, and dispensed into the vessels prior to the test. The system can easily change media types between tests.

The gravimetric delivery system assures accurate and reproducible media dispensing. Various fill volumes in different vessels – from 250 mL to 1,000 mL– are possible and are therefore ideal for DOE studies. During a basket method, media can be replaced automatically for two stage dissolution testing.

→ Media filling along vessel wall



Dosage Form Introduction

For paddle testing, dosage forms are stored in an 8-position carousel on the top of each vessel – protected from the media vapors. Inlets allow for all types of dosage forms: all tablet sizes (introduction diameter: 18 mm), sinkers. Almost any magnetic sinker larger than 15 mm in its smallest dimension (including magnetic Japanese sinkers) can be used with the system.
Dosage form introduction for basket and paddle methods is automated and simultaneous. For basket methods, a robotic arm sequentially attaches all the baskets containing the dosage form on their respective shaft.

→ Robotic arm attaching basket to shaft

→ Capsules in sinkers

→ Tablets in 8-position carousel

Sampling

The AT MD system uses automated cannulas to simultaneously withdraw samples (see picture on page 2). All sampling probes are equipped with temperature probes recording a temperature from each vessel when sampling.

For accurate and reproducible sampling on all channels and at each time point, the AT MD has 6 automated piston pumps – for filtered sample transfer. The integrated filter station automates the change of 25 mm syringe filters on all 6 channels at each run, each sampling point, or at media change. Samples are collected and stored in tubes or closed vials and can be analyzed by either a UV-Vis or LC device.

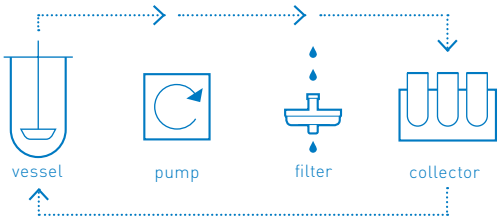
→ Filter station for 25 mm syringe filters

→ SOTAX recommends PALL Life Sciences Automation Certified filters

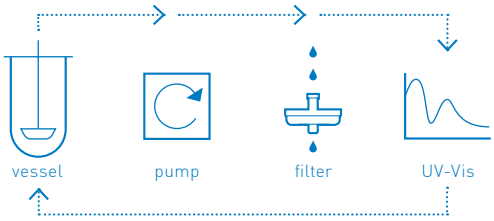
Data Analysis & Reporting

SOTAX systems offer sample collection, storage, and UV-Vis integration. These options can be combined in a variety of analytical configurations and reconfigured should needs change.

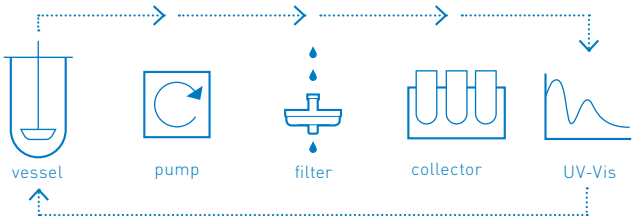
Off-line Systems:
- Scalable collection and storage of samples in tubes or vials
- Protection of samples from temperature and light degradation
- Automated sample collection reduces sampling variability



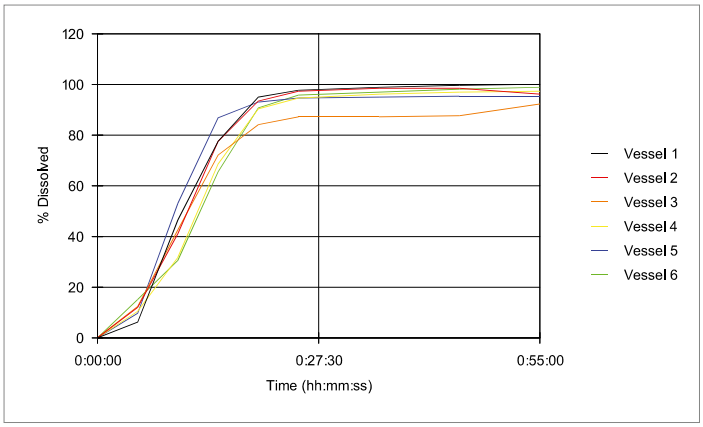
UV-Vis On-line Systems:
- Automated UV-Vis measurements for real time results
- Avoids sample transfer errors
- Dissolution software for data acquisition and analysis; no separate software required



UV-Vis On-/Off-line Systems:
- Fraction collection and/or UV-Vis measurements for sample archival or UV-Vis immediate comparison
- Provides flexibility for sample analysis and method development



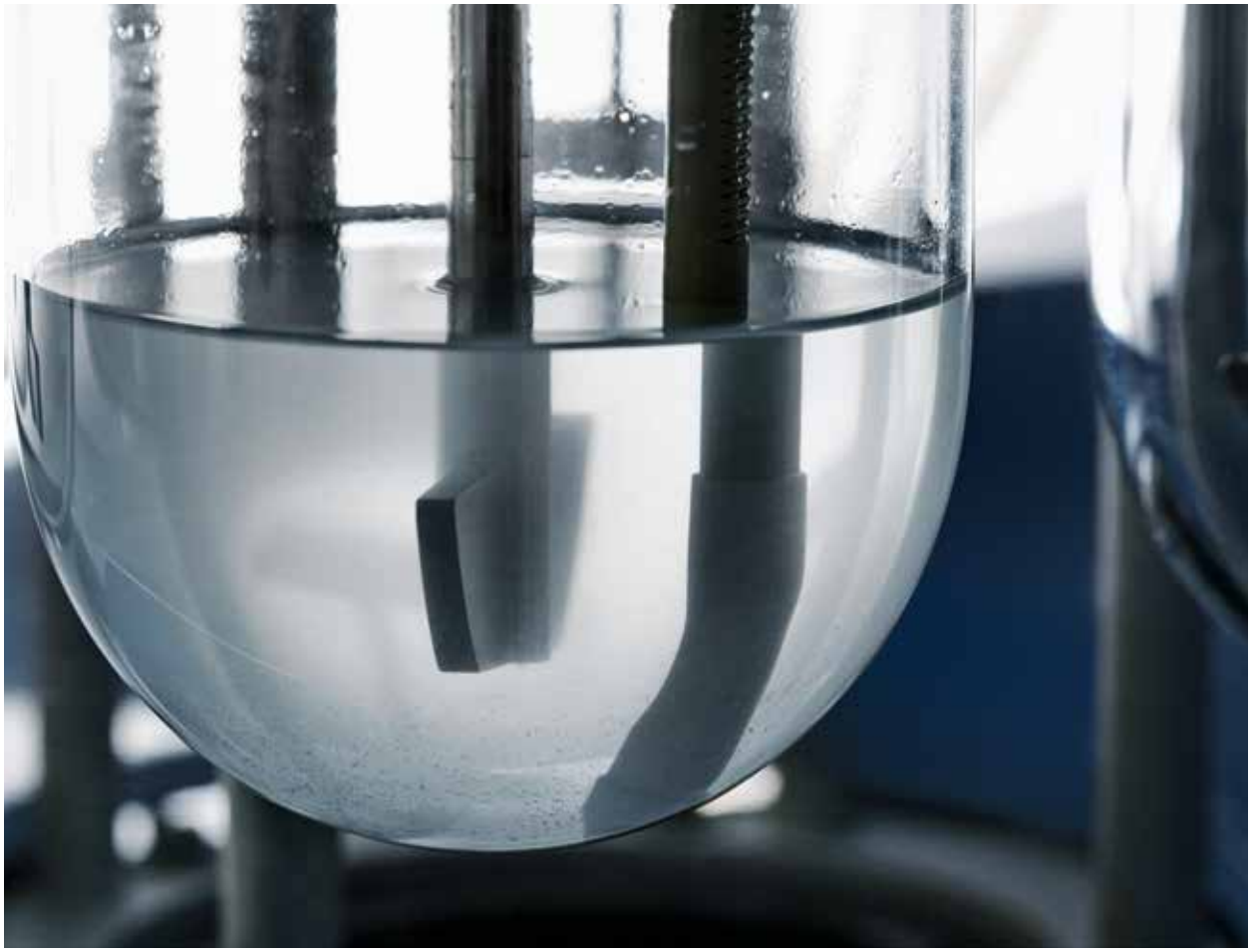
	Sample % Dissolution.					
	Group One					
Time (hh:mm:ss)	Vessel 1	Vessel 2	Vessel 3	Vessel 4	Vessel 5	Vessel 6
0:00:00	0.00	0.00	0.00	0.00	0.00	0.00
0:05:00	6.21	12.03	12.41	10.47	9.70	15.13
0:10:00	46.55	41.12	42.67	31.81	53.15	30.65
0:15:00	77.59	77.59	72.16	68.66	86.90	65.56
0:20:00	95.04	93.49	84.18	90.39	93.10	90.78
0:25:00	97.76	97.37	87.28	94.66	94.66	95.82
0:35:00	98.92	98.53	87.28	96.21	95.04	96.98
0:45:00	99.70	98.53	87.67	96.98	95.43	98.15
0:55:00	100.09	96.21	92.33	97.37	95.43	98.92



The MD software is 21 CFR Part 11 compliant, controlling all aspects of data capture and analysis with customized reporting and exporting. It allows data export to ELN/LIMS, user-group configuration and report configuration. MDsoft is a flexible software package designed to fulfill R&D and QC requirements.

→ Dissolution profile data

→ Dissolution report



→ Vessel emptying after dissolution run

Cleaning

Cleaning is essential for fully automated systems as it prevents carry-over and cross-contamination between individual dissolution runs. All baskets and sinkers are removed by the robotic arm. All vessels are emptied using a purging system. Cleaning can be done with cold and/or hot DI water and/or with dissolution media.

Associated Services

Technical Services

Global. Reliable. Customer-focused. The SOTAX Global Service Network is available worldwide, whenever and wherever you need us.

- System installation and qualification
- User training
- Preventive maintenance
- Technical support (first line responder training)
- Repairs
- Updates, upgrades, and customization
- Compliance services (cGMP compliant qualification: IQ, OQ, PQ, MQ, PVT, and customer-specific qualification)
- Service contracts
- Relocations

Application Services

At SOTAX we engineer solutions for development and quality control.
We support you with expertise at each step of your process:

Feasibility study	Secure your instrument investment with complete and independent data
Method development	Save time and resources, reaching your other deadlines
Method transfer	Secure method transfer in details up to automation scale-up possibilities
Method validation	Validate your developped method to get a complete method package immediately applicable
Application support at installation	Screen and anticipate your application potential hurdles as soon as the system arrives
Application training	Use the advices of dissolution experts to shorten your optimization phase
GMP / GLP analysis	Outsource with confidence your dissolution testing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