




AT 70smart Fully Automated Dissolution System

Fully automated from media preparation to data reporting
Batch up to 40 lots of Apparatus 1 or 2 methods including the use of sinkers
Powerful DoE screening capability with up to 8 different media per batch
Analyze samples on-line with a UV or inject directly to an HPLC
Supported by the 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?

Increase Productivity

Fully automated dissolution improves the productivity in the lab by automating the routine tasks of filling and cleaning vessels. A batch of up to 40 unattended lots can be run in a row. These can be for the same product, or connect up to 8 different media types for automated DoE screening.

Reduce Time-to-Market

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.

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.

Enhance Safety

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

Return on Investment

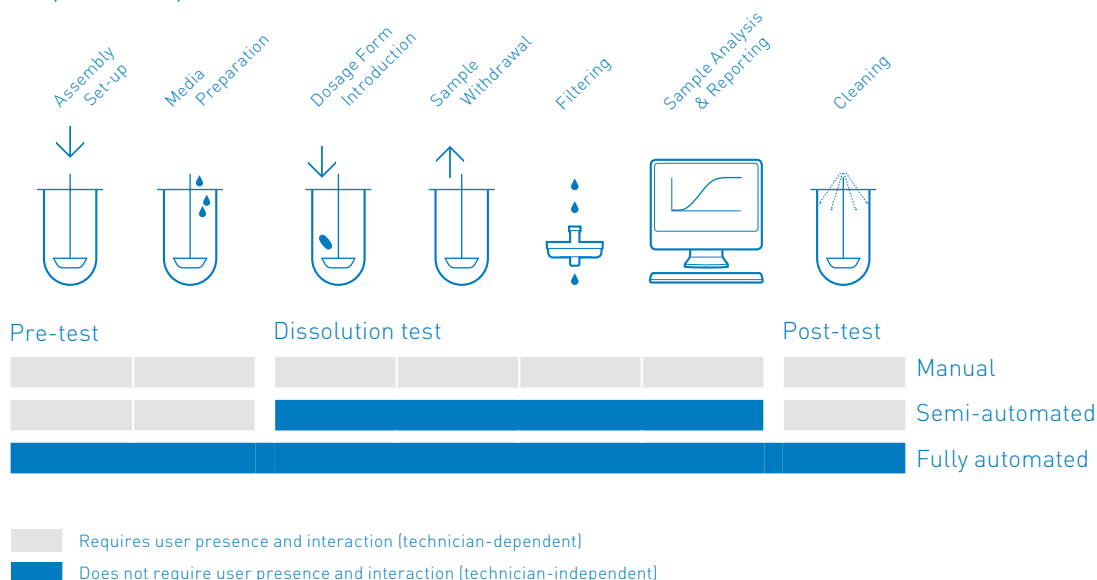
Go beyond the auto-sampler and automate the tedious filling and cleaning of vessels. Time can now be reallocated towards mission critical activities helping to reduce process cycle times by > 80%.

Dissolution Automation Levels

Choosing the level of automation that best fits the throughput requirements, process steps, and laboratory operating procedures, 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.

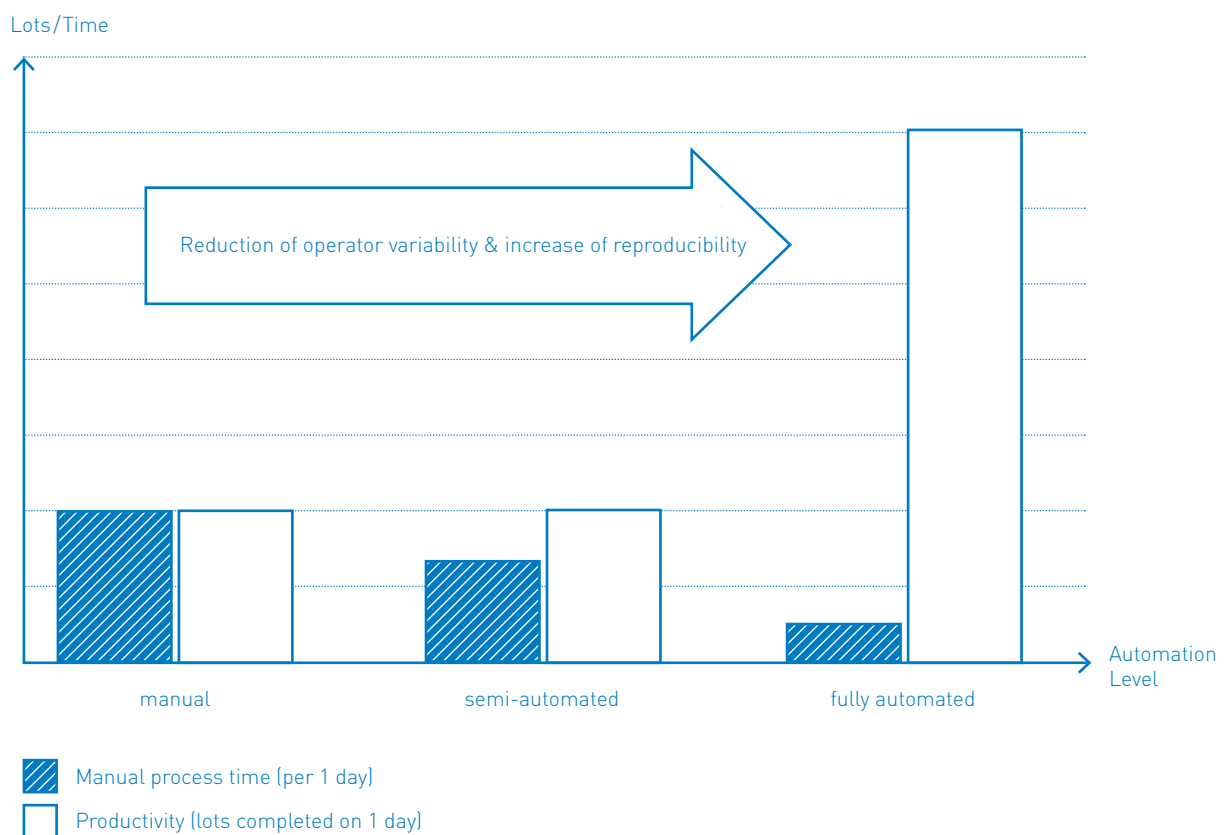
Fully automated steps

Fully automated systems automate the complete dissolution process – from the vessel filling through the entire dissolution test including end cleaning. Automating the complete cycle allows running up to 40 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. 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.



→ 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 AT 70smart Fully Automated Dissolution System

From pre-run to post-run system cleaning, SOTAX streamlines your workflow through the design of features that guide method development and simplify routine operation. With hundreds of systems in operation worldwide, SOTAX sets the benchmark for fully automated dissolution testing.

The AT 70smart BS 60 can handle basket, paddle, and methods requiring sinkers. By automating vessel filling and cleaning steps, much of the hands-on time required to run up to 40 lots of dissolution in a row is eliminated. The ability to use 8 different media per batch allows the user to either run several different products in a row or to use the system as a DoE tool in formulation screening.

The AT 70smart is driven by the 21 CFR Part 11 compliant WinSOTAXplus Advanced Dissolution Software. The design of SOTAX dissolution systems is compliant with all harmonized pharmacopeia requirements for paddle and basket methods.

The SOTAX AutoCompliance™ (Compliance by Design) concept with fixed shaft height and vessel auto-centering ensures reproducible and compliant vessel-shaft assembly without any manual adjustment. From this set-up, through the complete dissolution test, to mechanical calibration (executed by SOTAX Services with the MQD Mechanical Qualification Device): all compendial requirements are satisfied.

← HollowShaft™ automatic sampling with minimum hydrodynamic perturbation

→ AT 70smart dissolution system



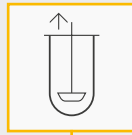
Media Preparation



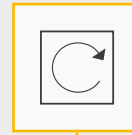
Dosage Form Introduction



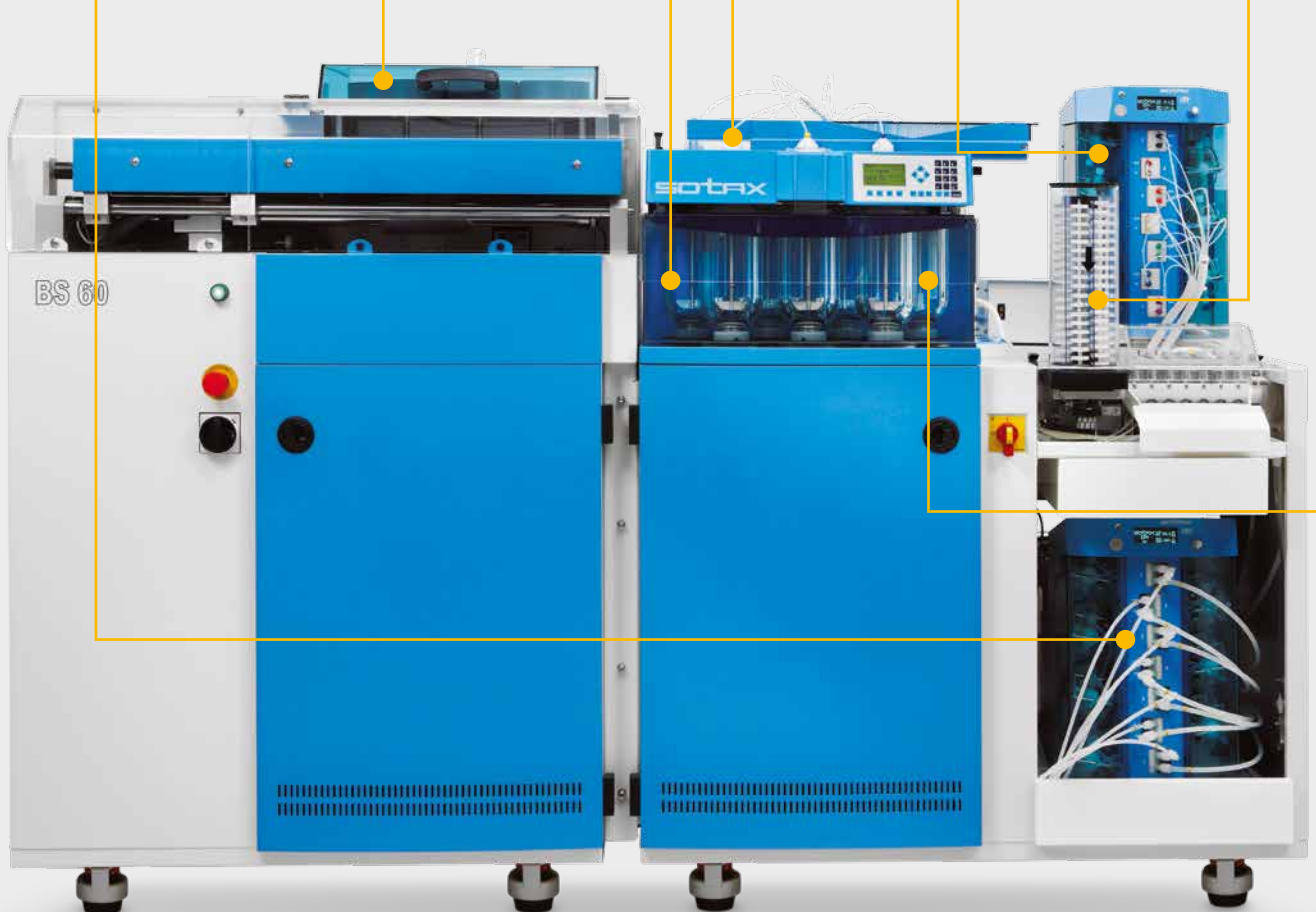
Sampling



Pumping



Filtering



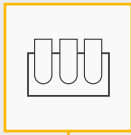
BS 60 Basket Station (only needed for USP 1 methods)

Used for basket (USP 1) tests, the BS 60 Basket Station holds 10 batches of baskets, transports them accurately between basket station and AT 70smart dissolution bath before and after the dissolution test, and handles the used baskets after the test.

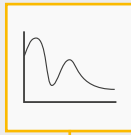
AT 70smart Dissolution System (incl. pumps and filter station)

Used for USP 1 and 2 dissolution tests, the system holds up to 40 batches of tablets. An integrated tank and pump prepares and fills the vessels with media prior to the dissolution test. A tablet magazine automatically and simultaneously drops samples into each vessel, and temperature and pH are monitored throughout the run in the reference vessel. The CP 7-35 Pump and the FS 7 Filter Station, integrated in the AT 70smart, withdraw, filter, and deliver samples to the SAM Sample Manager. Using power washing jets and pressured air for drying, the AT 70smart completes each run with a programmable cleaning cycle.

Collecting



Reading



Analyzing



Cleaning



SAM Sample Manager

The SAM Sample Manager, a multi-needle liquid handling system, is capable of simultaneously collecting samples from all 7 of the AT 70smart vessels. An optional single needle and LC injection valve can independently dilute and inject samples for LC analysis.

Analytical Device (e.g. UV-Vis or LC)

The AT 70smart system can integrate various analytical devices:

UV-Vis spectrophotometers:
SOTAX' own UV-Vis solution, the Specord Plus 200 or Specord Plus 210 UV-Vis spectrophotometers, can be fully integrated, just like other UV-Vis device brands.

LC instruments:
The AT 70smart system is compatible with all LC's capable of contact closure functionality.

Software

WinSOTAXplus Advanced Dissolution Software is 21 CFR Part 11 compliant. This powerful data management software is based on an SQL database architecture.

For LC On-line configurations, WinSOTAXplus is compatible with the existing and validated LC software.

Automated Steps



Media Preparation

Up to 8 different media (including concentrates, media with surfactants, and bio-relevant media) per sequence of up to 40 tests can be automatically heated, degassed (under vacuum or helium), and accurately dispensed simultaneously into the vessels through the hemispheric valves prior to the test. The use of concentrates reduces the space required for media storage and simplifies media handling and preparation.

To minimize preparation time between tests, dissolution tests in batch mode can be run continuously and without delay, media for the next run is prepared while the previous dissolution test is still running.

Hemispheric valves in the vessels allow simultaneous full or partial media changes within individual basket and paddle methods, which makes the AT 70smart ideal for media screening. For two stage dissolution testing on paddle and basket methods, media can be added or replaced automatically (half / full change).

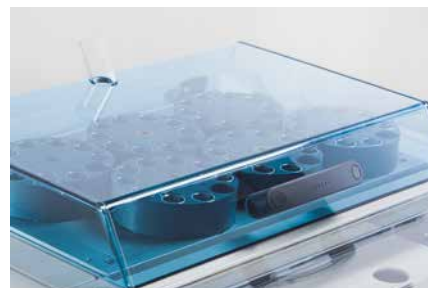


→ Simultaneous media dispensing into the vessels through the hemispheric valves



Dosage Form Introduction

For paddle testing, dosage forms are stored in a tablet magazine. To protect samples from moisture and to avoid human error during the filling, the magazine is protected by a numbered cover. To fit a large variety of dosage forms, different magazines are available.



For basket methods, baskets are positioned into 10-position carousels in the BS 60 Basket Station. A cover with an integrated gas purge to eliminate humidity within the basket station protects the dosage forms from moisture. SOTAX also provides customized solutions to increase the capacity of the system and to overcome inherent challenges for sample introduction (e.g. sticky tablets and capsules, pellets, etc.).




To minimize time between tests, all baskets containing the dosage form are attached simultaneously on their respective shafts. Integrated sensors check the presence of each basket. The AT 70smart then introduces all dosage forms automatically and in parallel for both basket and paddle methods.

→ Arm attaching baskets to shafts

→ Basket carousels

→ Different tablet magazines



Sampling

The AT 70smart system uses the HollowShaft™ technology to simultaneously withdraw samples (see picture on page 6). This technology has been proven and is recognized as compliant sampling by the USP. For decades this technology has been trusted by AT 7 and AT 7smart users around the world.

It eliminates probe effects due to hydrodynamic disturbances and guarantees reproducible sample withdrawal at a compliant sampling height. Using this same sampling system in manual, semi and fully automated dissolution systems simplifies method transfer between systems at differing levels of automation.

Media temperature is monitored throughout the run in the reference vessel.

For accurate and reproducible sampling on all channels and at each time point, the AT 70smart has a 7-channel ceramic piston pump – for filtered sample transfer with a possible filter porosity down to 0.2 micron. The integrated FS 7 Filter Station automates the change of 25 mm syringe filters, at each run, media change or each sampling point. Samples are then automatically transferred for analysis.



→ Automated change of 25 mm syringe filters

→ SOTAX recommends PALL Automation Certified Filters

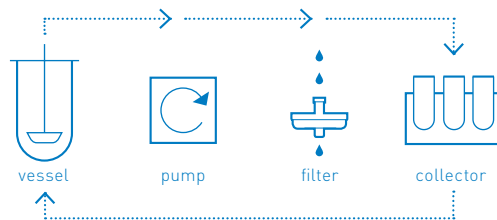


Data Analysis & Reporting

For sample collection, storage and UV-Vis or LC analysis, the AT 70smart system allows for various different analytical configurations integrating the following components. These options can be reconfigured should needs change.

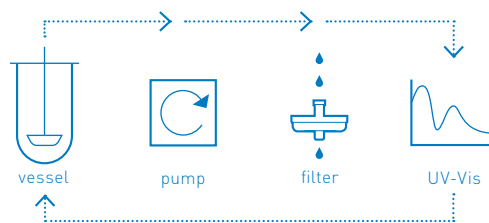
Off-line Systems

- Component included: SAM Sample Manager
- Scalable collection and storage of samples into standardized tubes or vials
- Sample protection from temperature and light degradation
- Use of vertical space to reduce footprint



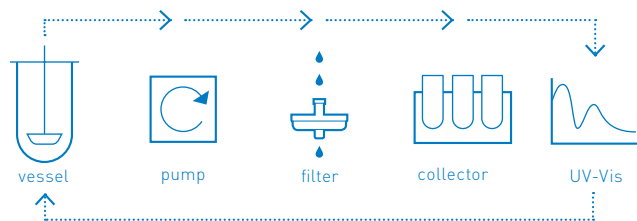
UV-Vis On-line Systems

- Component included: Specord UV-Vis spectrophotometer (or others)
- Automated UV-Vis measurements for real time results
- Allows unattended dissolution run, results being stored and saved automatically



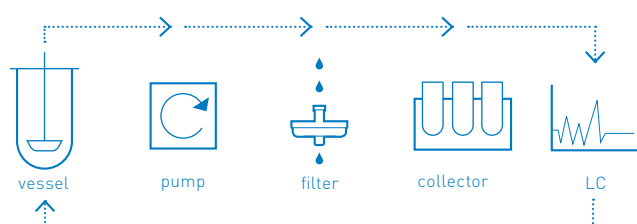
UV-Vis On/Off-line Systems

- Components included: SAM Sample Manager and Specord UV-Vis spectrophotometer (or others)
- Flexibility: fraction collection and/or UV-Vis measurements for sample archival or UV-Vis/LC immediate comparison



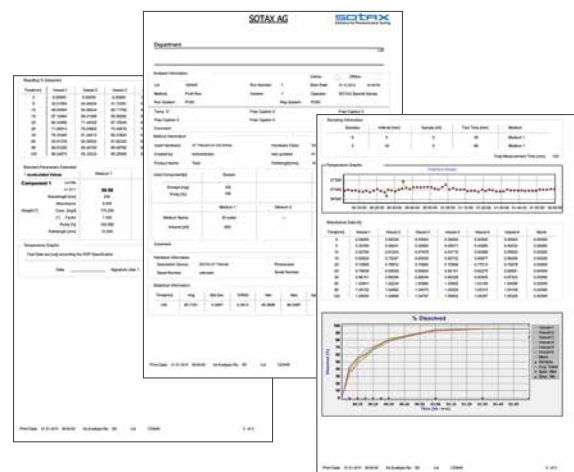
LC On/Off-line Systems

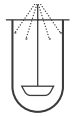
- Components included: SAM Sample Manager and LC hardware
- Automated LC injections for real time results
- Allows back-up sampling
- Sample dilution
- Sample flow controlled by WinSOTAXplus compatible with existing LC software



WinSOTAXplus software is 21 CFR Part 11 compliant and Windows XP / 7 (32 and 64-bit) compatible, controlling all aspects of data capture and analysis with customized reporting and exporting. It allows bi-directional data transfer to ELN/LIMS, user-group configuration and report configuration. WinSOTAXplus is a flexible software package designed to fulfill R&D and QC requirements in a client-server architecture.

→ [WinSOTAXplus Advanced Dissolution Software](#)



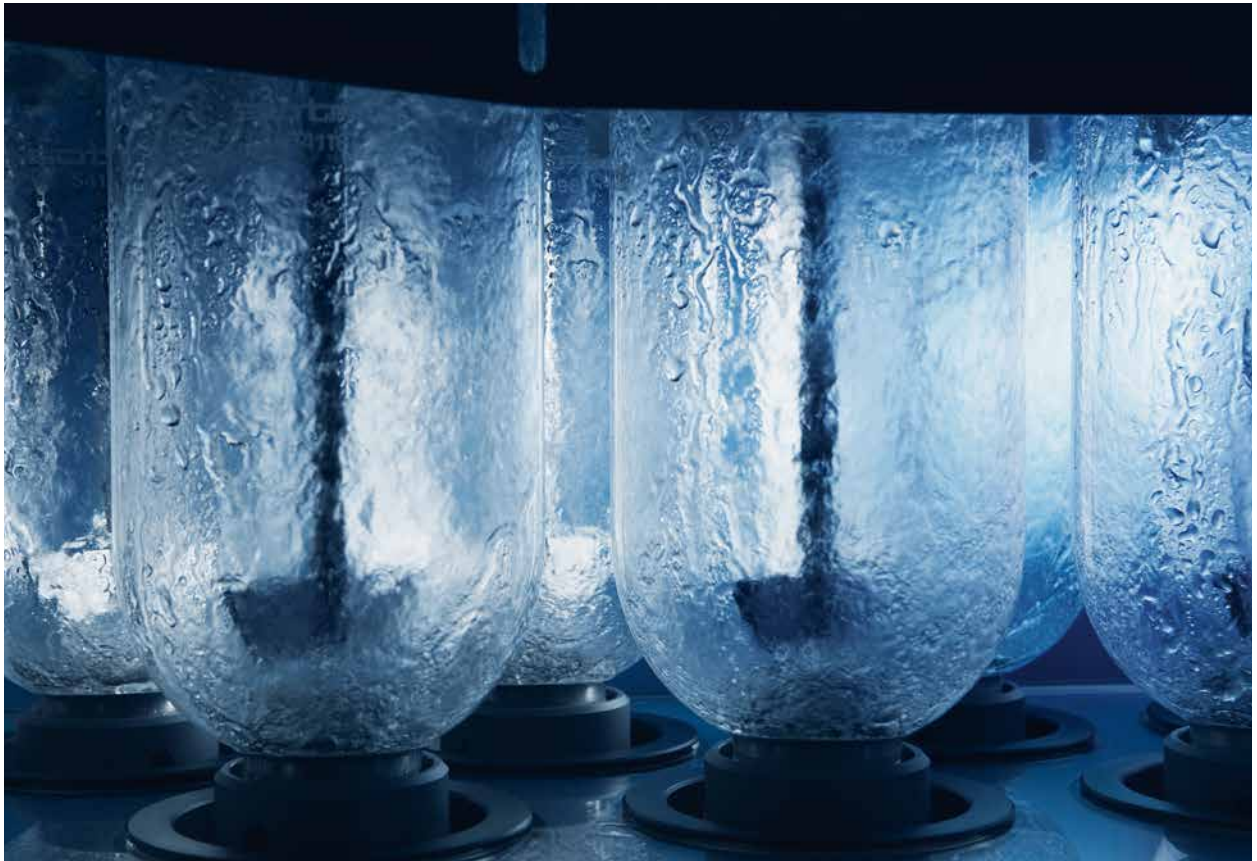


Cleaning

Cleaning is essential for fully automated systems as it prevents carry-over and cross-contamination between individual dissolution runs.

The AT 70smart uses the hemispheric valve for rapid simultaneous vessel emptying and cleaning. Sinkers, pellet cartridges, and undissolved dosage form components (e.g. osmotic pump tablets) are also removed in parallel through the valve, while all baskets are removed and collected by the basket station BS 60.

All vessels are efficiently and simultaneously cleaned with a series of 14 rotating power washers. Cleaning procedures for vessels and sampling lines can be programmed to include pressurized cold/hot/DI water and/or dissolution media.



→ Thorough and simultaneous cleaning
of all vessels

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	Outsource the validation steps required for implementing manual, semi- and fully automated methods
Application support at installation	Screen and anticipate your application potential hurdles as soon as the system arrives
Application training	Use the advice of dissolution experts to shorten your optimization phase
GMP / GLP analysis	Outsource your dissolution testing with confidence

SOTAX Worldwide

Europe

Switzerland (HQ Europe)

Aesch/Basel

P Tech Support +41 61 487 5460

P Office +41 61 487 5454

info@sotax.com

Czech Republic

Prague

P Tech Support +41 61 487 5460

P Office +420 246 039 260

info@sotax.com

France

Saint-Louis

P Tech Support +41 61 487 5460

P Office +33 3 8970 0846

info@sotax.com

Germany

Lörrach

P Tech Support +41 61 487 5460

P Office +49 7621 16 5635

info@sotax.com

Great Britain

London

P Tech Support +44 20 8349 6946

P Office +44 20 8349 6947

info@sotax.com

Italy

Bergamo

P Tech Support +41 61 487 5460

P Office +39 035 21 9555

sotaxitalia@sotax.com

Americas

USA (HQ Americas)

Westborough, MA

P Tech Support +1 508 544 4040

P Office +1 508 417 1112

sotaxusa@sotax.com

Canada

Brampton

P Tech Support +1 800 931 4151

P Office +1 905 494 0114

sotaxcanada@sotax.com

Asia-Pacific

India (HQ Asia-Pacific)

Mumbai

P Tech Support +41 61 487 5460

P Office +91 22 42 95 01 -91 / -92

sotaxindia@sotax.com

China

Shanghai

P Tech Support +41 61 487 5460

P Office + 8621-6135 6268, ext. 205

sotaxchina@sotax.com