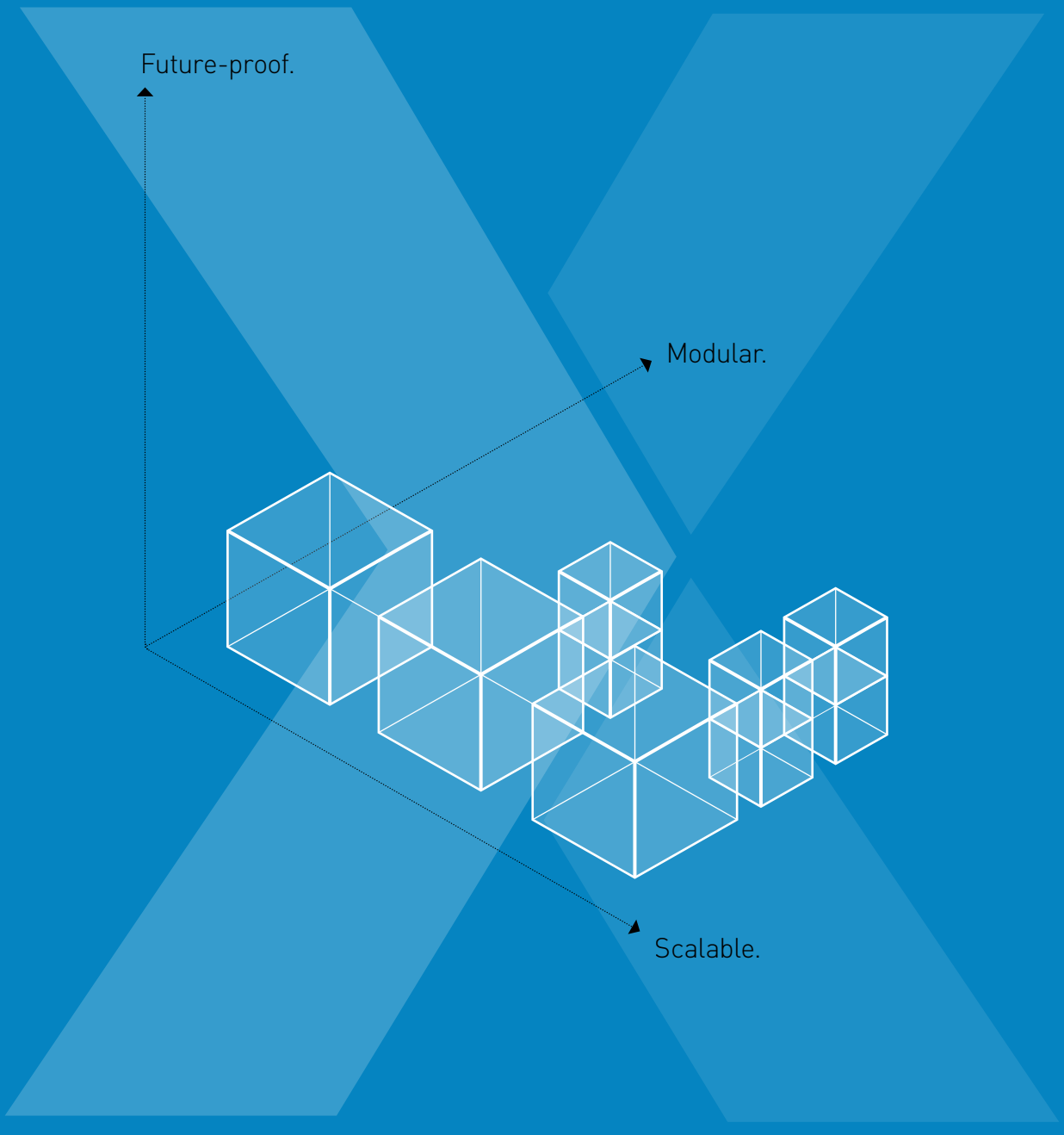

sotax
Xtend™
Modular. Scalable. Future-proof.
Xtend™ Dissolution Line
Manual & Semi-Automated
USP 1, 2, 5, 6


Future-proof.
Modular.
Scalable.

The Xtend™ Dissolution Line

The ability to flexibly respond to permanent change in today's fast-paced pharmaceutical environment can make the difference between success and failure. Fast time-to-market requirements, outsourcing, relocations, shift of manufacturing capacities and short return on investment considerations ask for equally flexible testing solutions in R&D and QC laboratories. The fully scalable and modular Xtend™ concept is 100% based on this basic premise and allows you to tailor dissolution testing to both your current and future needs – making your investment future-proof.

Modular.
Standardized Xtend™ modules such as the dissolution bath, pump, filter station, and sample manager can be flexibly combined for different automation requirements – from manual to semi- and fully automated dissolution systems. Irrespective of the configuration, all modules and components of the Xtend™ Dissolution Line are extremely robust having been designed for the most demanding conditions of a fully automated system running 24 hours per day.

Scalable.
The Xtend™ Dissolution Line simplifies method transfer – making scale-up from R&D to QC with different throughput requirements and changing workloads easier than ever. From qualification to writing SOP's: keep in place what is already used, described and validated.

Future-proof.
Secure your investment today and flexibly manage tomorrow's demands. With a proven track record of thousands of systems installed world-wide and more than 40 years of experience in dissolution testing, the Xtend™ Dissolution Line is a safe investment. All system modules incorporate the very latest technology for maximum efficiency and provide for highly reliable dissolution testing based on precision-made high quality components.

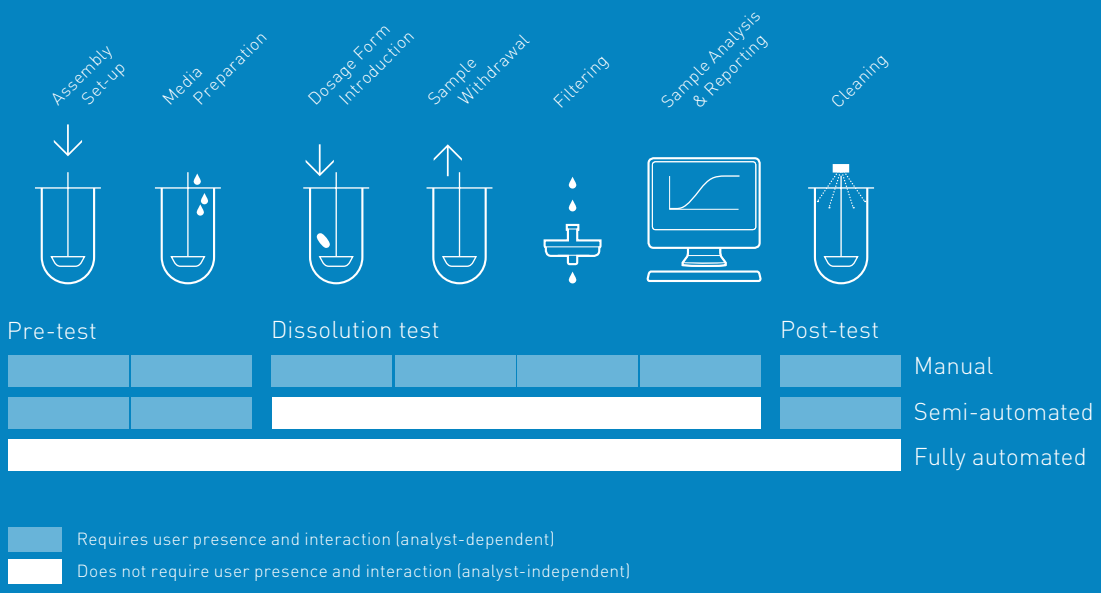
Ready for tomorrow. Today.

SWISS QUALITY
ISO 9001

Automating Dissolution

Defining the level of automation that best fits the product and throughput requirements can help to ensure reproducibility and standardization of your dissolution test.

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



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

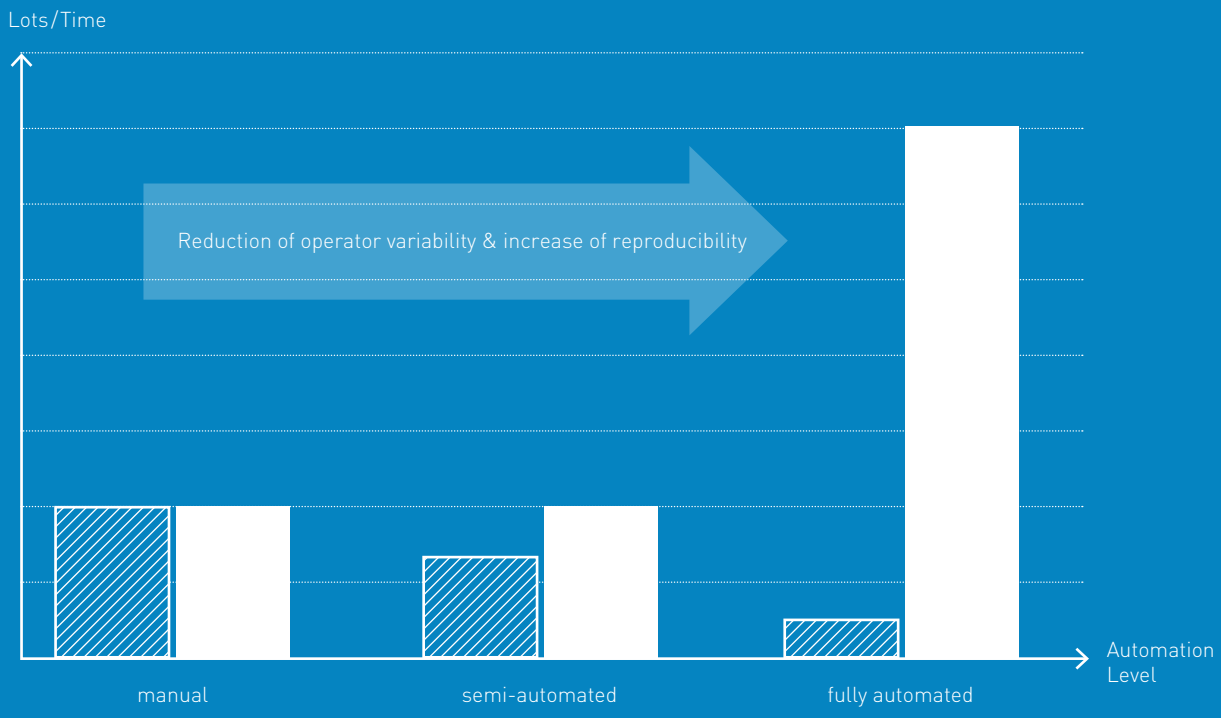
Semi-automated
Semi-automated systems ensure that all sequential steps during the dissolution run are reproducibly executed without requiring user interaction until the postrun activity.

Fully automated
Fully automated systems automate the complete dissolution process – from preparation to cleaning. Several tests of the same or different products can be executed directly after each other – without requiring any user action.

The main drivers for selecting your level of automation are:

- Number of tests per day
- Duration of test
- Number of sampling time points
- Analytical method
- Number of additional process steps (e.g. pH changes)

Automation and standardization of individual process steps ensure repeatability and allow handling of higher volumes. For high throughput requirements, semi- and fully automated dissolution systems offer a fast return on investment (ROI), shorten test cycle times, reduce operator variability and therefore improve reproducibility.



Manual process time (per 1 day)

Productivity (lots completed on 1 day)

Immediate Release test (30 mins) based on:

- UV-Vis analytical configuration
- 1 sampling point
- 1 operator

Experts in Automation

With more than 40 years of experience in automation, SOTAX dissolution systems are proven to be a safe investment. Our manual, semi- and fully automated solutions are used in R&D and QC departments every day. Compliance by design, reliable technology and competent local service have made SOTAX dissolution systems the preferred choice of leading pharmaceutical companies all over the world.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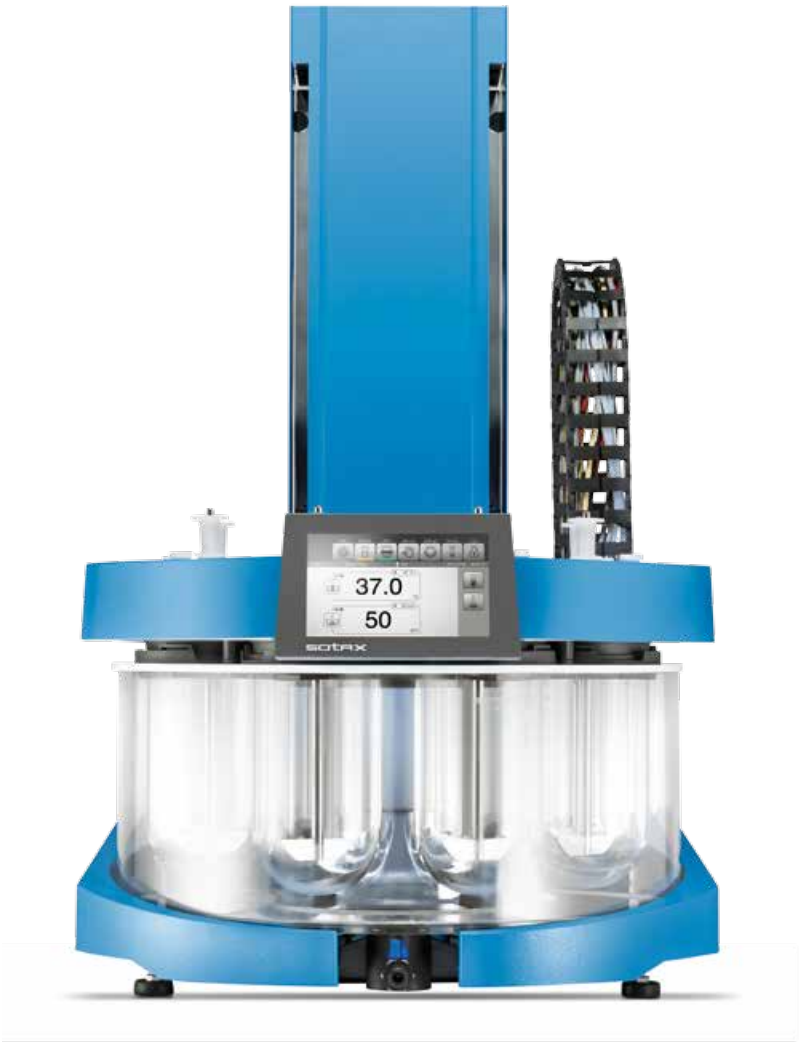
AT Dissolution Apparatus

The AT dissolution bath is the heart of the Xtend™ Dissolution Line. Whether used as a manual apparatus or as the core component in an automated dissolution system – the AT has been designed for the most demanding environments. Built on the success of preceding SOTAX dissolution systems, the AT can be flexibly configured for USP 1,2,5,6 dissolution methods. Its unique design combines robust quality components with state-of-the-art technology to guarantee reproducible testing conditions, day after day. Depending on the required automation level, the AT can be flexibly extended with additional Xtend™ modules – making method transfer for increased throughput requirements easier than ever.



→ AT Dissolution Apparatus

Innovative Circular Design

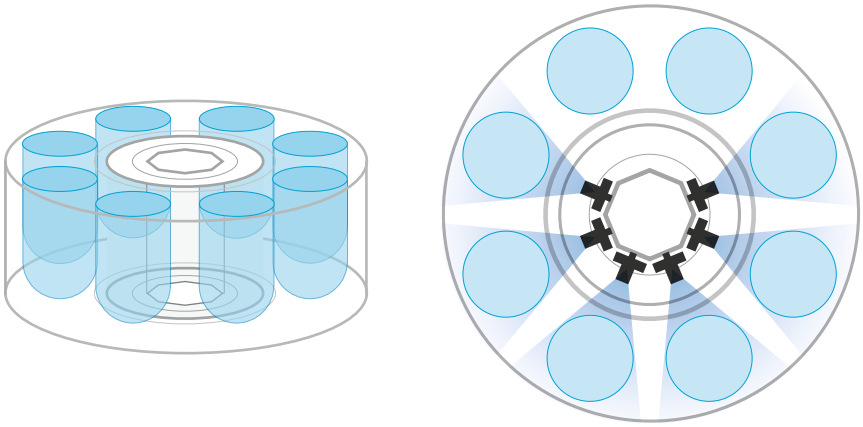
The AT dissolution bath with 6-8 vessels sets new standards for quick and easy operation. At the same time, it opens up a new dimension of observation possibilities for R&D visualization and OOS troubleshooting.

100% visibility
Understanding the release characteristics of formulations requires full visibility of samples during the dissolution test. Depending on your observation needs, the circular AT bath allows visual observation of each vessel from the outside and additionally from the inside using video monitoring. To view the behavior of samples from the bottom, an optional mirrored base plate is available.

CenterView™ video monitoring
The unique CenterView™ design provides perfect visualization and video recording of release processes in each vessel. Located in the center of the dissolution bath, all cameras can be adjusted and controlled for height and focal distance. For optimum visibility, indirect light is integrated into this space-saving design.

Precise temperature control
Like its predecessor model, the AT dissolution bath has been optimized for ideal water circulation to ensure extremely high temperature homogeneity during the test.

Easy handling and cleaning
From fast filling and draining of the water bath with quick-connector, self-priming circulation pump, to motorized lift function all handling and cleaning processes of the AT have been optimized for simple and fast execution. When adding test medium or removing vessels, the vertically lifted shaft drive provides excellent accessibility during all change-over and cleaning processes.



→ Circular bath design with central video monitoring of each vessel

Compliance by Design

The AT dissolution apparatus fully complies with all harmonized Pharmacopeia requirements and features "built-in" compliance without any adjustment.

The proven SOTAX AutoCompliance™ concept with fixed shaft height and vessel positioning guarantees 100% compliance without requiring time-consuming adjustments by the operator. For fast change-overs, quick-lock systems and a vertical bath closing mechanism (manual or motorized) provide for simple handling processes.

Auto-centering vessels
Time-consuming vessel set-up is unknown with the AT's auto-centering quick-lock system. Locking rings, which are fixed on the base plate, guarantee highly accurate vessel centering and allow analysts to insert or remove vessels within seconds. Each vessel is certified and closed with an individual cover limiting evaporation.

→ Auto-centering vessels with quick-lock system

Fixed shaft height
Proven to have the lowest wobble ratings in the industry, the AT incorporates the same shaft design as previous SOTAX dissolution baths. All shafts are self-centering and no adjustment of shaft height is required – maintaining the highest level of precision while making change-overs fast and simple.

→ Fixed shaft height with quick-lock system

→ Assisted closing mechanism for precise centering and positioning

Highest repeatability
During dissolution tests, stirring speed and temperature are continuously monitored. To ensure reproducible conditions, all shafts and vessels are identified with a unique serial number.

Fully documented qualification
The AT has been designed to facilitate highly accurate mechanical calibration anytime. Using the innovative Mechanical Qualification Device (MQD), all required procedures and measurements can be easily performed and results are automatically documented according to the current FDA guidelines on enhanced mechanical qualification.

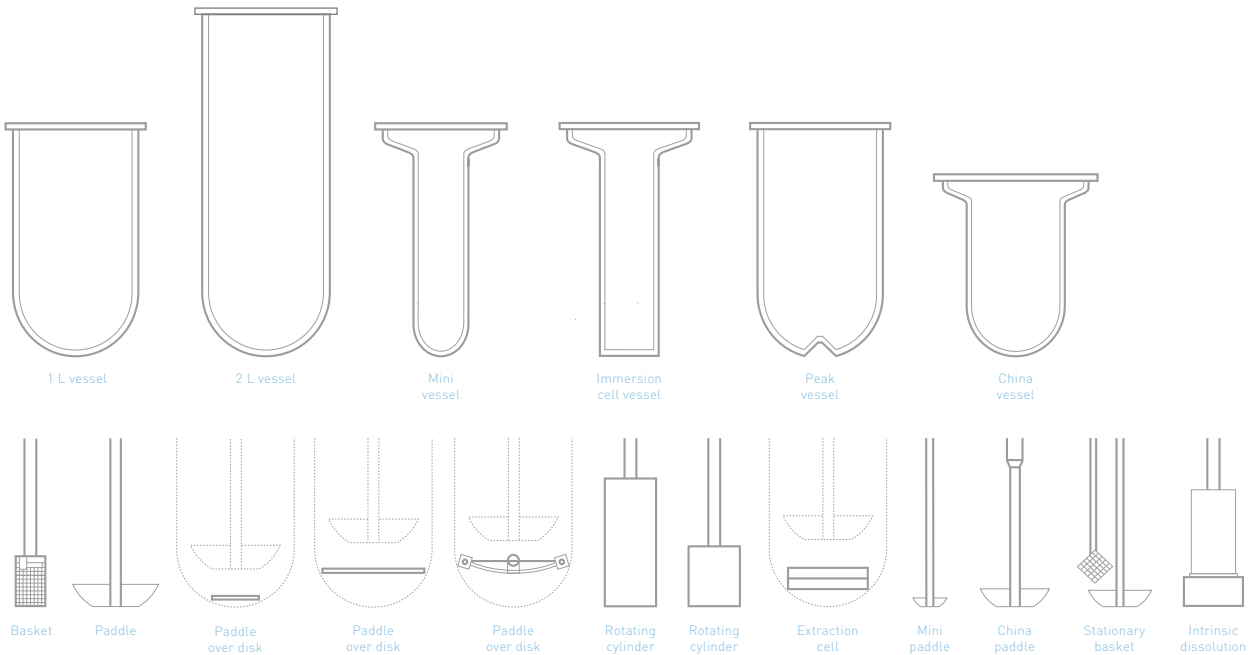
Flexibility Maximized

Large inlet dimensions allow for a wide variety of tablet and sinker types to be introduced manually or automatically. For full flexibility, the AT can be operated with various stirrer and vessel types.

Suited for all dosage forms
From standard tablets to capsules with large sinkers – the AT dissolution bath is capable of handling virtually all dosage forms. Samples are protected from media before test start. As the inlets are closed during the test, media evaporation is prevented.

Different vessel styles
For full flexibility, the AT bath accommodates a broad variety of different vessel styles – from certified standard glass vessels to polycarbonate or low actinic glass vessels, 1 or 2 liter vessels, mini vessels, China vessels, and peak vessels.

USP 1,2,5,6 and more
Developed for USP 1,2,5,6 methods, the AT allows testing with different compliant and also non-compliant stirrer designs. All parts are made of high quality material, are serialized and certified.



User-friendly with EasyTouch™

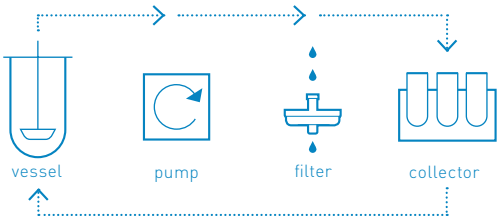
Simple and intuitive touch screen operation makes test set-up and method programming easier than ever. Logical, icon-based menu structures and multi-language capability reduce analyst training times to a minimum.

The large integrated 5.4" color touch screen sets new standards for efficient operation. User rights settings, method programming, data visualization, data transfer and reporting are readily available at the touch of a button. Using the built-in USB port, methods can be conveniently exchanged between different AT installations – eliminating redundant programming tasks. Various communication ports allow local and network printing, status monitoring via TCP/IP and full system control by PC software whenever needed.

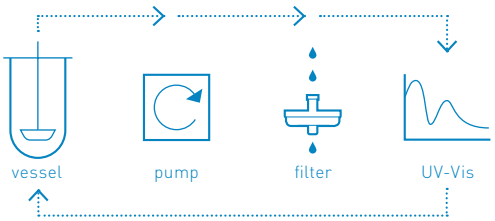
Analytical Configuration

The AT dissolution bath can be flexibly combined with additional Xtend™ Modules for automated sample collection and storage – including UV-Vis and LC integration.

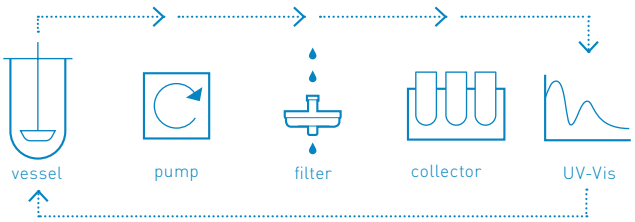
Off-line Systems
- Scalable collection and storage of samples into standardized tubes or vials
- Sample protection from temperature and light degradation
- Use of vertical space to reduce footprint



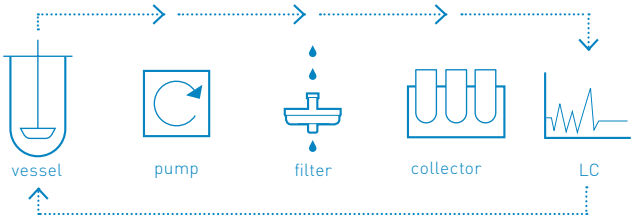
UV-Vis On-line Systems
- Automated UV-Vis measurements for real time results
- Single dissolution software for raw data acquisition and flexible calculation
- Automates the manual sample transfer which can be a source of manipulation error
- Allows unattended dissolution run, results being stored and saved automatically



UV-Vis On/Off-line Systems
- Flexibility: fraction collection and/or UV-Vis measurements for sample archival or UV-Vis/LC immediate comparison



LC On/Off-line Systems
- Automated LC injections for real time results
- Automates the manual sample transfer which can be a source of manipulation error
- Allows back-up sampling
- Sample dilution
- Space-saving integrated system
- Sample flow controlled by WinSOTAXplus compatible with any existing LC software



Workflow Configuration

From media preparation to system cleaning – the Xtend™ Dissolution Line allows streamlining the entire workflow to guide method development and simplify routine operation.

Media Preparation

Accurate media preparation plays a vital role in all subsequent processes. The MPS Media Preparation Station allows operators to degas, heat, and dispense the exact volume of dissolution media required for each method.

Degassing at the USP and FDA recommended levels, the MPS is a mobile unit assisting in bringing 10 – 20 L of degassed and heated media to your dissolution system. By inserting the dispensing nozzle into individual vessels, precise and gravimetrically validated dispensing of media at 1'500 mL per minute without re-aeration is achieved. Once dispensing has been completed, the MPS can be simply connected to the next DI water inlet to start its automated cleaning routine – while the dissolution test runs.

← Gravimetric volume confirmation with balance

→ MPS Media Preparation Station


3827

Complete Sampling Solutions

Automating the sampling process improves accuracy, reproducibility and simplifies method transfer. Standardized modules for sample withdrawal allow sampling tailored to your application.

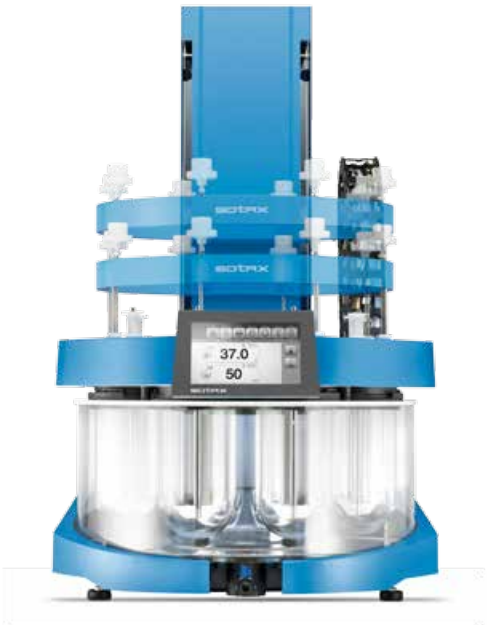
For dissolution sample withdrawal, four key factors must be considered: height reproducibility, automation potential, hydrodynamic impact and possible coupling to temperature monitoring. Automating the process with simultaneous sampling and automatic pumping improves time and volume accuracy. Based on your requirements, the Xtend™ Dissolution Line offers a wide variety of manual and automatic sampling possibilities:

- Simple manual sample withdrawal using a glass pipette
- Stand-alone type sampling probe with additional pipette guide
- Stationary cannula in different materials and diameters for sampling with disposable syringes
- Automatic simultaneous sampling with the unique HollowShaft™ – reducing hydrodynamic perturbation
- Automatic simultaneous sampling with cannula and AutoLift™ for maximum flexibility

	Glass pipette or sampling probe	Glass pipette or sampling probe with pipette guide	Stationary cannula	HollowShaft™	Automated cannula (AutoLift™)
Height reproducibility	–	●	●	●	●
Automation potential	–	–	●	●	●
Reduction of hydrodynamic impact	–	–	–	●	–
Temperature coupling	–	–	–	–	●

← **HollowShaft™**
Automatic sampling with minimum hydrodynamic pertubation

→ **Automated cannula**
with AutoLift™ for maximum flexibility in sampling and monitoring



Simultaneous Sample Withdrawal

The accuracy of sample transfer from the dissolution apparatus to the sample manager and/or analytical device largely depends on the accuracy of the pump used and on its ability to push or pull liquids through the filters.

As sample transfer occurs simultaneously on all channels, any pump used must contain 6-8 equivalent modules. In addition to traditional peristaltic pumps used in UV-Vis on-line systems, the Xtend™ Dissolution Line also offers additional sampling options with the SAM Sample Manager.

Syringe Pump Module
Containing 6-8 precision syringes, the module is integrated in the SAM dispensing head for off-line dissolution systems. This simple and space-saving design allows simultaneous transfer of samples through filters with a porosity down to 1 micron into test tubes or LC vials. For seamless integration, the syringe pump module can be controlled directly via the EasyTouch™ user interface or alternatively by WinSOTAXplus Dissolution Software.

CP Piston Pump Module
The CP Piston Pump Module is the ideal choice for automated systems and it can also be used to perform media addition. To reduce the overall footprint, the CP Module is fully stackable with other Xtend™ Modules. The ceramic piston head design is valve-free, requires minimum maintenance and does not need any priming. Fully controlled by either the EasyTouch™ user interface or WinSOTAXplus Dissolution Software, the powerful CP Module can pull and push through filters (pull: filter porosity down to 0.45 microns; push: filter porosity down to 0.2 microns).

← **Syringe Pump Module**
Simple solution for off-line dissolution systems

→ **CP Piston Pump Module**
Flexible and fully stackable solution for all automated dissolution systems

Reproducible Filtration at each Time Point

Filtering dissolution samples prior to analysis is essential to the accuracy of dissolution results. The Xtend™ Dissolution Line can be operated with different membranes and filters of various porosities.

Membrane filters

The 25 mm membrane filters can be used with sampling probes, automated cannulas and HollowShaft™. Integration directly into the suction head makes these filters both economical and user-friendly.

Syringe Filters

The 25 mm syringe filters offer 100% flexibility as they can be universally used on disposable syringes, sampling probes, stationary cannulas, automated cannulas, HollowShaft™, CP Modules and FS Filter Stations. Ideal for simplified method transfer, they can be used on all automation levels. During method development in R&D, the variety of porosities allow the user to find the filter required for analytical finish. In QC, the robustness and strength of this filter housing guarantees consistency of the filtration surface. Syringe filters are Luer-locked and therefore robust and easy to use.

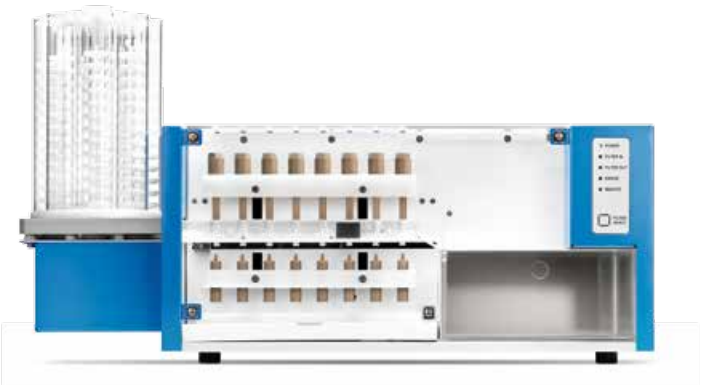
PALL Life Sciences

→ SOTAX recommends PALL Automation Certified Filters

FS Filter Station

To avoid saturation and clogging of syringe filters, it may be necessary to exchange them after each sampling point. The FS Filter Station automatically exchanges filters and can hold up to 424 filters for filtering through 6, 7, or 8 channels. Robust and fast in operation, the module guarantees liquid-tight circulation at each time point. To reduce overall system footprint, it can be stacked with other Xtend™ Modules.

→ **FS Filter Station**
Automatic exchange of syringe filters for all channels



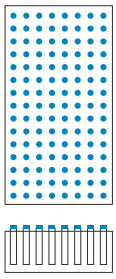
Universal and Efficient Sample Management

Workload increase or method changes often call for maximum flexibility and scalable sample management – in addition to safe and reproducible collection and storage.

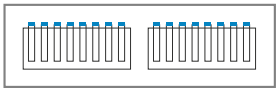
The SAM Sample Manager can be used either as a simple fraction collector to collect and store samples in standardized vials and tubes, or as an advanced sample manager to add or replace media, dilute, and/or inject samples in an LC or UV-Vis spectrophotometer.

Controlled by the EasyTouch™ user interface or by WinSOTAXplus Dissolution Software, the SAM will fit with all dissolution methods – independent of the automation level chosen. Like all Xtend™ Modules, the SAM can be stacked with the CP Piston Pump Module and/or the FS Filter Station to reduce overall system footprint.

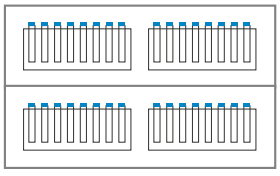
Available in three versions (S/M/L), the module allows vertical storage of samples in up to 3 levels. Its capacity can also be extended horizontally for semi-automated double systems or for an increased number of time points.



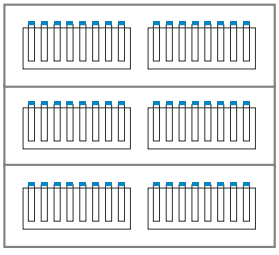
1 rack = 120 samples
8 channels
15 time points



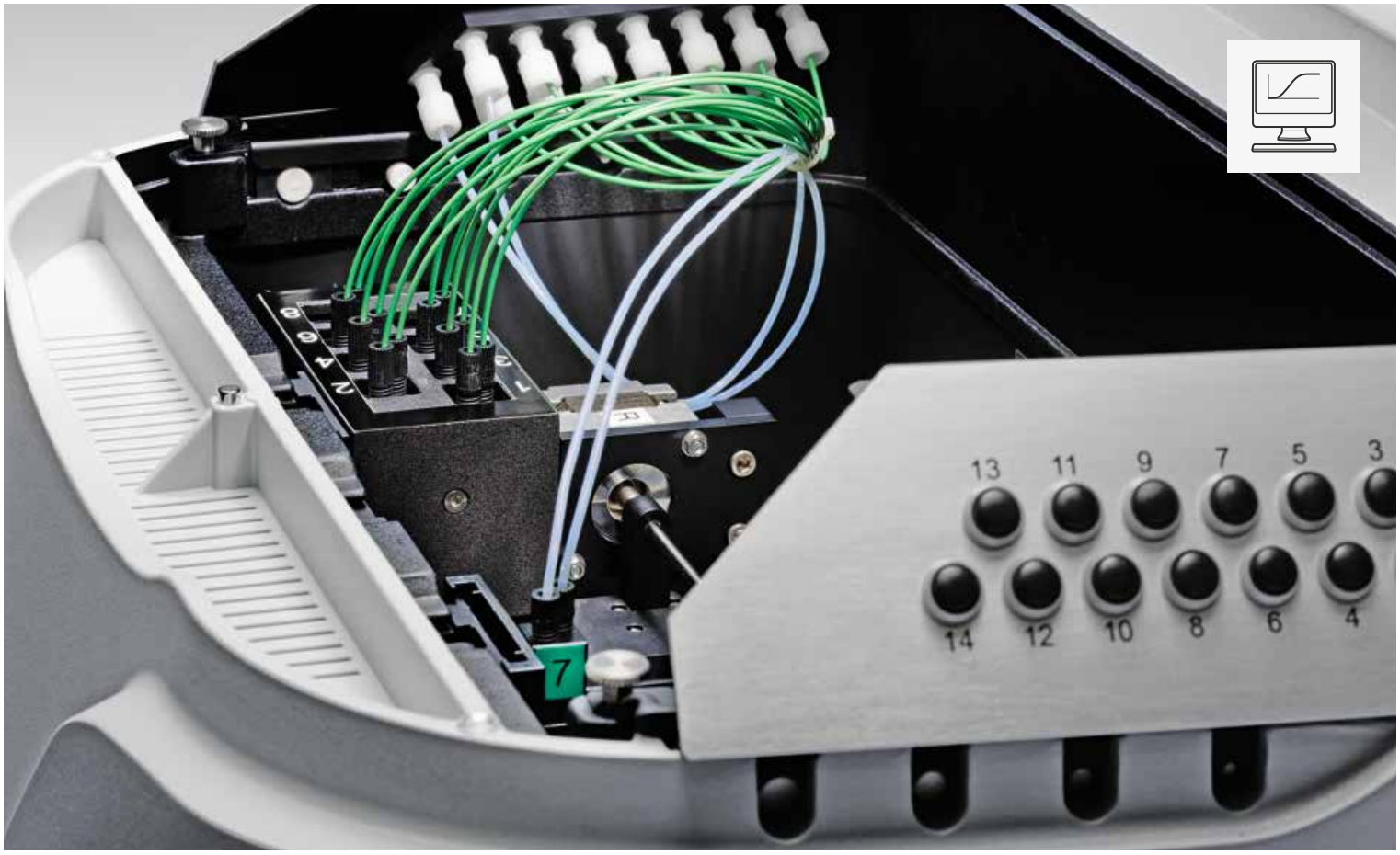
SAM S



SAM M



SAM L



Sample Analysis and Reporting

UV-Vis or LC analysis being the final step of the dissolution process, the Xtend™ Dissolution Line allows integration of different analytical processes and combines results in a powerful data management software.

UV-Vis Analysis
The WinSOTAXplus Dissolution Software is 21 CFR, Part 11 compliant and full control of all common UV-Vis spectrophotometers. Dissolution samples can be withdrawn, filtered and measured in "Absorbance" at single- or multi-wavelength in flow-through cuvettes. The readings are calculated, reported and stored in an SQL database.

Seamless integration with Specord Plus®
SOTAX also offers its own UV-Vis solution: the Specord Plus 200 or Specord Plus 210 UV-Vis spectrophotometers are fully integrated in the Xtend™ Dissolution Line. Both systems exceed Pharmacopeia requirements and have a true double beam with reference compensation. Using two symmetrical 8-position cell changers, they are ideal for double on-line and double on-/off-line system configurations. As a standard, the Specord Plus series comes with a 10 year warranty on optics.

LC Analysis

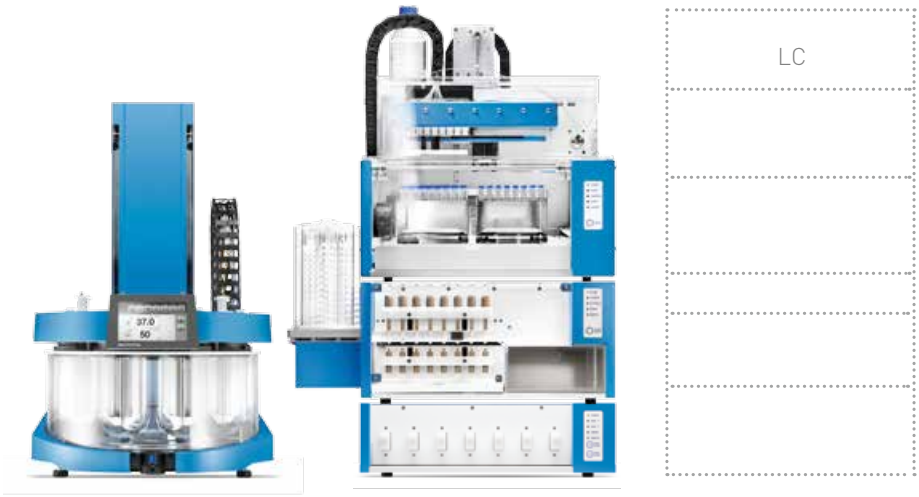
LC on-line systems automate manual sample transfer for unattended operation – thus maximizing your LC throughput, increasing efficiency and reducing human errors. The Xtend™ Dissolution Line offers two different solutions to seamlessly connect to your existing LC system:

MF MultiFunction Interface for Real Time Sample Transfer

Compatible with all LC's capable of contact closure functionality, the MF MultiFunction Interface transfers your dissolution samples as soon as they are withdrawn from the vessel. Handling up to 8 standards, the MF is a robust and simple solution adapted to fast LC analysis.

SAM Sample Manager for Scheduled Sample Transfer

Compatible with all LC's capable of contact closure functionality, the SAM LC on-line system stores and protects samples in standardized tubes or vials as soon as they are withdrawn. The SAM adds and replaces media if necessary and injects samples into the LC. The LC injection workflow is processed in parallel to the dissolution sampling with an independent injection syringe. Existing in three capacities, stackable with other Xtend™ Modules to save bench space and handling standards from ports or vials, the SAM is the most flexible dissolution sample manager on the market.

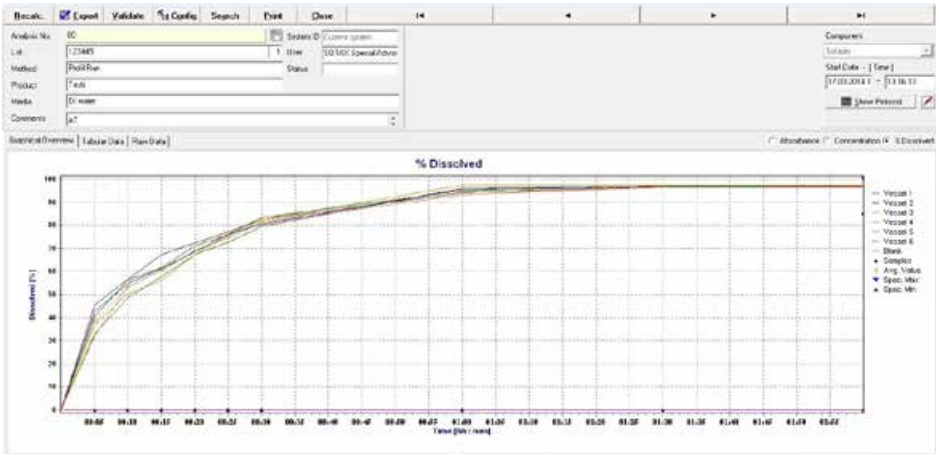


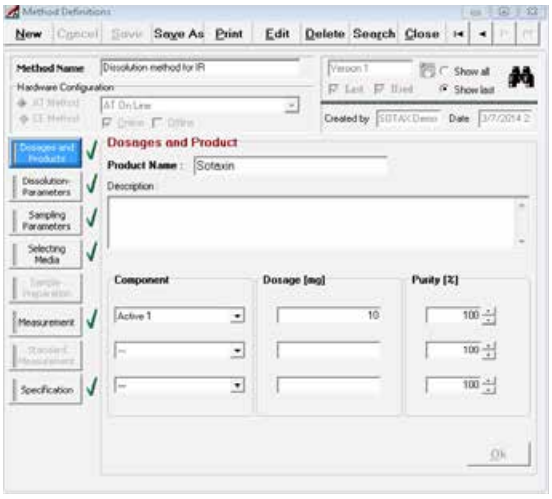
Professional Data Management

Developed in close cooperation with industry experts and system users, the WinSOTAXplus software is based on a deep understanding of today's dissolution user requirements and allows implementation of a fully 21 CFR, Part 11 compliant data management system for all Xtend™ configurations and automation levels.

The WinSOTAXplus software offers user-friendly control of your complete system. Whether used stand-alone or in a networked environment, the modern client-server architecture can be flexibly implemented for different needs. From data capture to analysis with customized reporting and exporting features – the software fulfills all R&D and QC requirements. For advanced data management, specific user-group definition and bi-directional data transfer to ELN/LIMS are available.

Simple batch analysis alongside assisted data review is possible with customized reports and method creation including product specifications. Spend less time on compliance paperwork with highlighted pass/fail reports alongside enhanced temperature, rpm, and pH recording throughout the test. Comprehensive standard monitoring and customized system suitability requirements are stored and executed per product to ensure proper SOP execution.





→ WinSOTAXplus Advanced Dissolution Software

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 data confirmation of automation capability on your products
Method development	Save time and resources by allowing SOTAX application scientists to develop your methods in accordance with your method development requirements
Method transfer	Use our trained hands to provide method training and facilitate the transfer of your dissolution methods across sites
Method validation	Speed rollout by allowing us to facilitate and document validation of your method on-site
Application support at installation	Screen your applications for ROI and develop an efficient plan for integrating automation into your laboratory
Application training	Come to our labs or invite SOTAX into yours to work with our application experts to streamline the dissolution workflow

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