sotax

APW & TPW
Automated Sample Preparation

Compliant automated preparation of up to 300 samples
Content/Blend Uniformity, Potency, and Related Substances Assays
Simplify extraction of difficult ER, CR, and tamper resistant formulations
Robust, reproducible, and fit-for-purpose methods

Why Automate Sample Preparations?

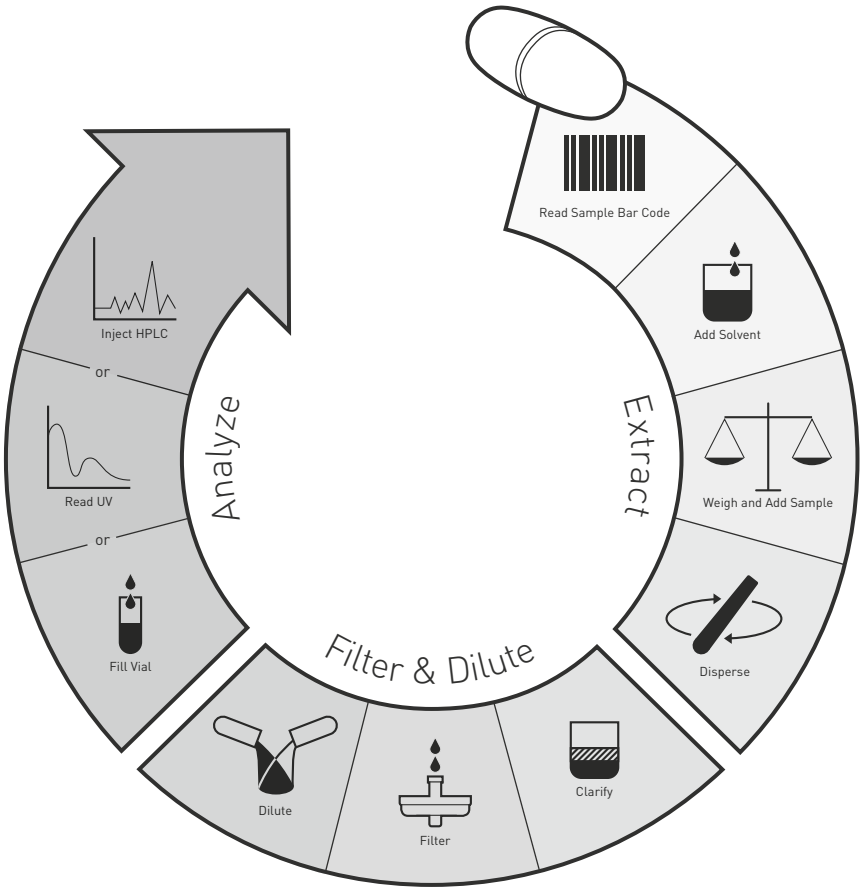
For Content Uniformity, Blend Uniformity, Potency, and Related Substances Assay

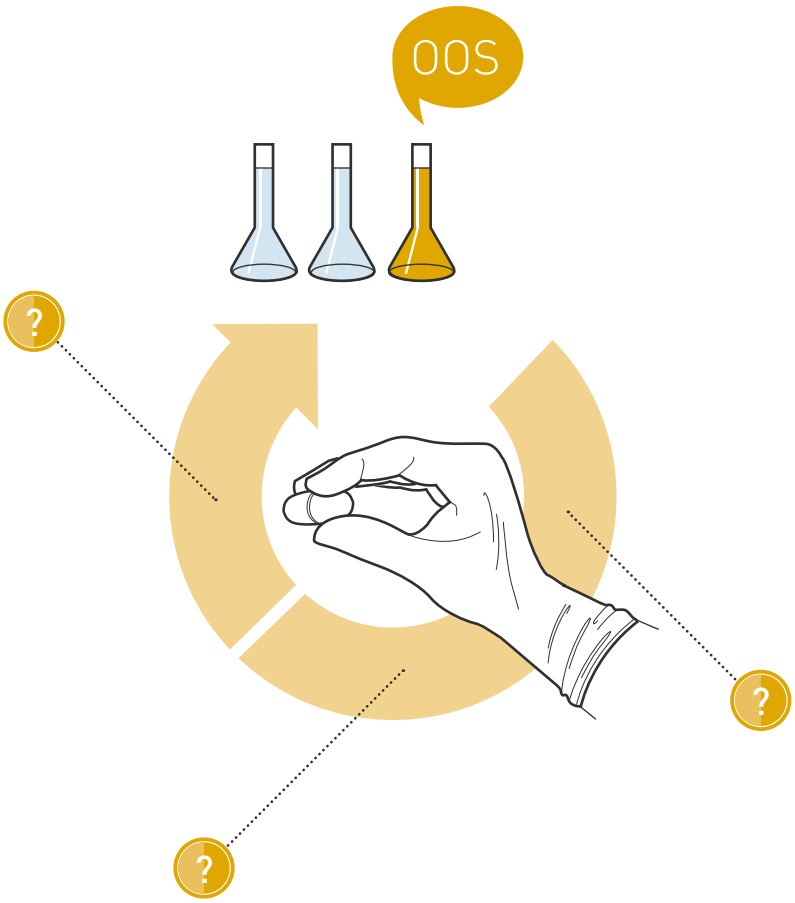
Sample preparation can be a very general term. When we talk about sample preparations at SOTAX, we're referring to the volumetric preparations of API, solid/liquid oral dosage forms, creams, and pastes.

Why automate? Automated Sample Preparation enhances laboratory productivity by minimizing resource allocation for repetitive tasks such as sample weighing, extraction, filtration, dilution, and transfer to analysis devices. This enables the repurposing of lab staff to mission critical tasks such as data analysis, reporting, and notebook documentation. Automated procedures can also reduce solvent usage and hazardous waste generation while improving analyst safety by minimizing exposure to hazardous reagents and samples.

Do you want to streamline your laboratory workflow? Automation facilitates processing labor-intensive samples for a broad spectrum of challenging formulations including tamper-resistant, osmotic pump, modified, extended, and delayed release. With robust focused extraction techniques the samples are consistently prepared across a variety of analysts and laboratories. Each step is gravimetrically confirmed and tracked in a secure database to ensure reproducible, high quality, traceable, compliant results.

Recent initiatives to incorporate QbD and Continuous Process Improvement principles into the drug product lifecycle management process have increasingly raised laboratory productivity expectations. The demand for more sample throughput with the same or reduced head count is being imposed on laboratories across the industry. With 100's of installations globally, processing hundreds of thousands of samples, SOTAX Automated Sample Preparation Systems have proven to be reliable and compliant solutions to enhance your laboratory's efficiency and accelerate the workflow.



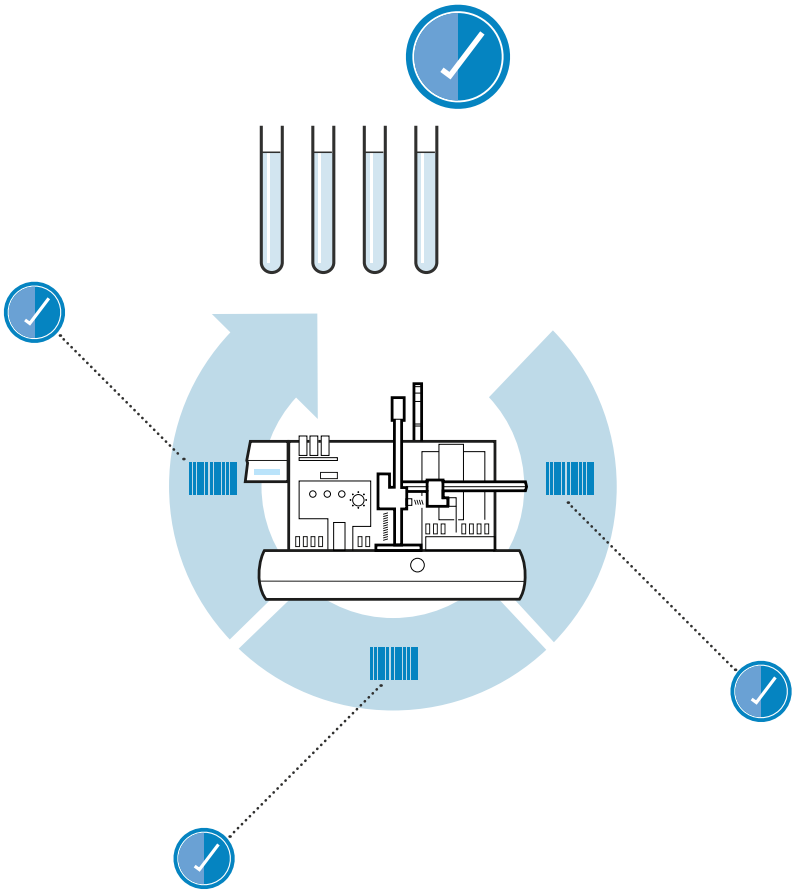


Manual

Out with the old ...
Volumetric glassware for tablet, capsule, and blend evaluations have long been the industry standard. Unfortunately, so have bottlenecks, OOS investigations, and excessive solvent costs.

Traditional sample preparation relies on technique-dependent and labor-intensive laboratory steps often requiring error-prone data transcription.

Coupled with the limited extraction efficiency of stirring, shaking, and sonication mechanisms, manual sample preparation is at the root of many time-consuming and costly lab investigations.



Automated

... and in with the improved!
Automate your sample preparations so that they are performed the same way every time. Each method step is confirmed gravimetrically, reported volumetrically, and documented electronically.

You will improve overall lab cycle times and reduce solvent costs.

APW and TPW

Enhanced for Greater Productivity

The APW and TPW Automated Sample Preparation Systems have recently been enhanced to provide even greater sample preparation productivity and reduced cycle time while streamlining your laboratory workflow. The TPW and APW provide productivity solutions to a broad variety of laboratories and applications. Typical products range from solid or liquid oral dosage forms for the pharmaceutical industry to tooth paste and lipstick for the consumer products industry. Regardless of the industry or the degree of regulation, these platforms maximize efficiency and throughput for a vast array of applications. From API to suspensions to tablets to medicated feeds, the TPW and APW provide a range of support from simple sample preparation to barcoded sample ID and preparation with on-line HPLC analysis and compliant data transfer to your validated CDS.

→ APW and TPW
Automated Sample Preparation Workstations

Fully Automated Steps

Extraction

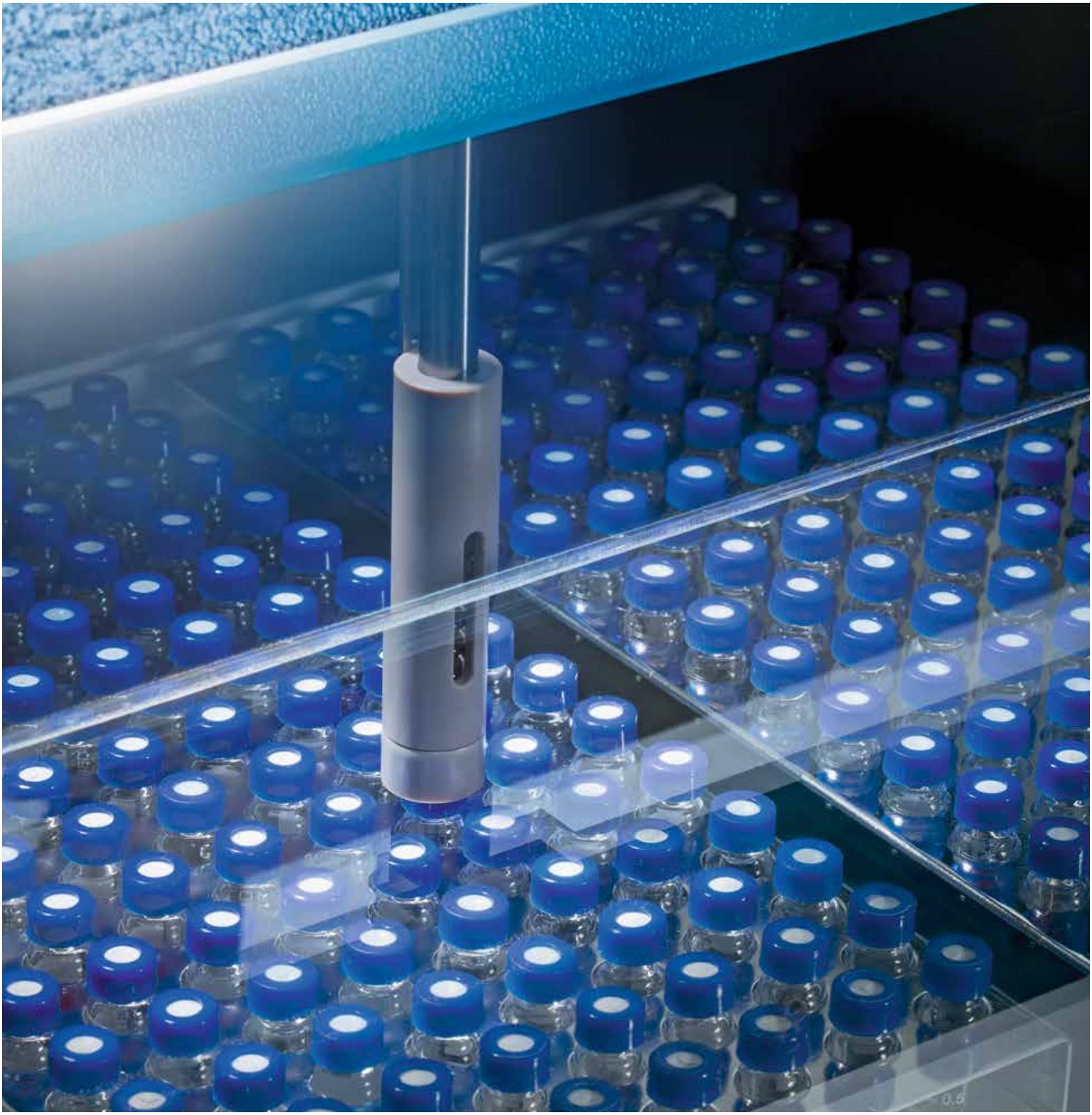
The TPW uses a high-shear homogenizer probe to provide a consistent wet grinding process to quickly extract samples. Alternately, the APW has a sonication probe coupled with a UV temperature sensor to deliver focused sample disintegration without overheating. With these tools, both TPW and APW can achieve efficient and reproducible extraction for even the most challenging of sample formulations. Cleaning of the extraction path between samples is easily programmed into the method to eliminate sample carry-over, ensuring that each sample is handled identically. The newly updated TPW and APW are enhanced to reduce cycle time by adding efficiency to the system cleaning process.

Filtration & Dilution

The TPW uses a fluid metering pump to filter extracted samples as they are transferred from the extraction vessel to test tubes. Both the TPW and the APW also support a syringe-driven filtration process to filter solutions from one test tube to another. Post filtration, both systems can perform up to 1:100,000 dilutions within a single method. Further dilutions are also possible using the "Method Overlap" feature. The volumes for all liquid handling operations are confirmed gravimetrically for added accuracy and precision. For every sample, the system audit trail combined with the advanced error handling capabilities provides a detailed and comprehensive record of the entire preparation process.

Analysis & Storage

Both units have HPLC injectors to support on-line HPLC analysis. A Waters Empower™ interface is also included to provide compliant data transfer to Empower™ for streamlined sample analysis with enhanced traceability. All result-critical sample preparation information is transferred to Empower™ as the TPW/APW sample run-list progresses. In addition to on-line HPLC analysis, samples can also be collected in sealed HPLC vials to support various off-line analyses. Finally, both the TPW and APW have the capability to transfer sample to a UV spectrophotometer to act as an autosampler for on-line UV analysis. The systems will then use an analog connection to trigger the UV to read the sample in accordance with the external UV instrument control program.



→ SAM Sample Manager

Collect samples with optional cooling for off-line analysis or further processing

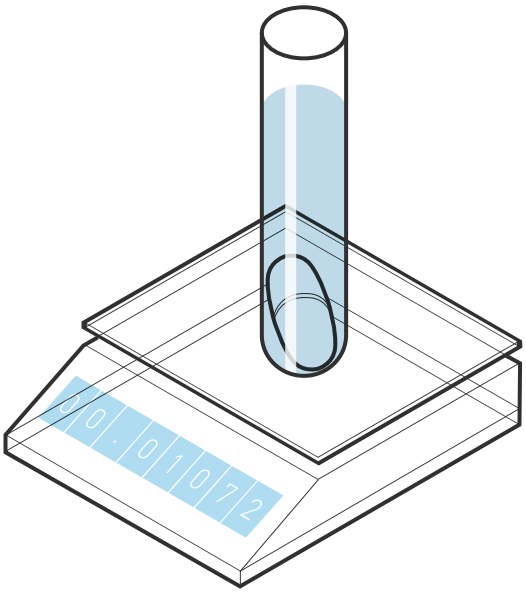
Benefits

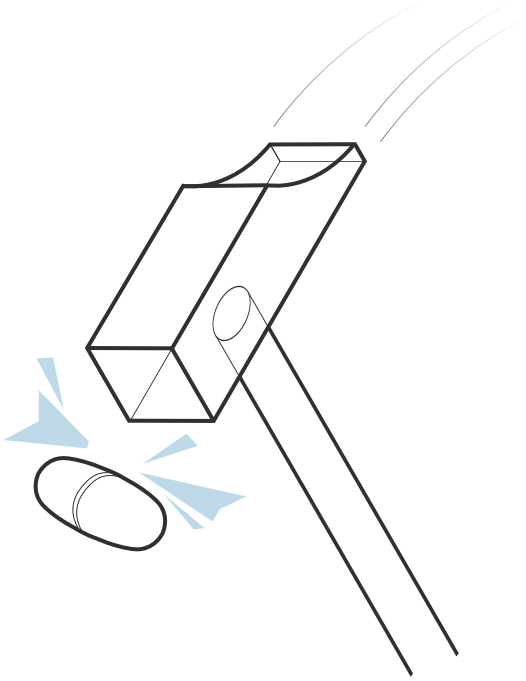
Perform High Quality Preparations

Automated Sample Prep means robust and reproducible preparation that is equivalent or superior to your manual analytical procedures. Robust and reproducible means that automation guarantees uniform sample history.

Sample weighing capabilities include 4- or 5-place weighing with automatic switching to 4-place mode for gravimetric confirmation of volumetric sample dilutions.

"Uniform sample history in automated sample preparation eliminates bias and error introduced by inconsistencies in manual preparation."





Extract Difficult Formulations

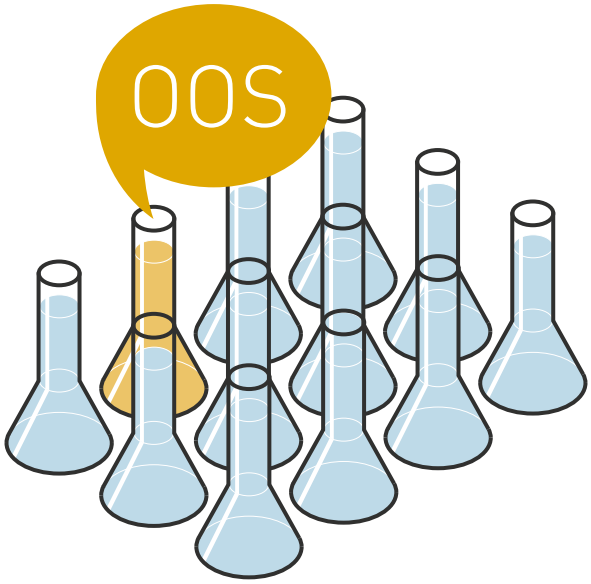
Products such as ER, CR, MR, osmotic pump, and tamper-resistant formulations present a difficult challenge to the manual sample preparation method. This can result in increased method complexity and raise the risk of OOS results. Due to the physics of the focused homogenizer and extraction vessel geometry, the TPW is able to quickly break and extract even the most difficult formulations.

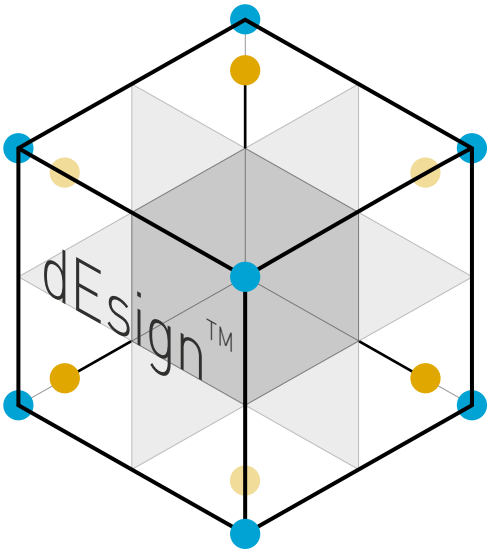
"Break away from the limitations of shaking and stirring. Homogenization provides superior extraction for even the toughest jobs."

Reduce and Simplify OOS Investigations

Deficiencies in laboratory investigations are a major source of warning letters in the pharmaceutical industry, accounting for 12 % – 15 % of 483s annually. With TPW and APW, each method step is gravimetrically confirmed and recorded in the secure database to ensure high quality consistent results. The TPW and APW audit trail provides a compliant and comprehensive history of the entire sample preparation process. In the event of an unexpected result, this audit trail ensures a well-defined assignment of root cause to simplify the laboratory investigation process.

"No more auditing of pipettes and volumetric flasks and no need to store glassware around the lab for weeks."





Automate Your Method Development

Our user-friendly software interface provides rapid assimilation of the TPW and APW platforms in all environments from academic to industry AR&D to the QC lab. Advanced developer options accelerate the method development process to facilitate Analytical Quality by Design (AQbD). AQbD pairs good scientific principles with quality risk management. Combined with the Empower™ interface, TPW and APW's powerful dEsign™ variables fully automate AQbD to ensure robust, fit-for-purpose methods that deliver consistent results throughout the method lifecycle. These powerful software functions allow you to plan and execute method development DOE activities quickly and efficiently. The easy-to-use and intuitive software interface streamlines the method transfer across sites.

"DOE and QbD for analytical methods are no longer just buzz words. TPW and APW are 'designed for experiments'... today."

Specifications

	APW	TPW
Max. Sample Throughput per Run	300 samples (extraction mode 1 & 2)	100 samples (extraction mode 1) 200 samples (extraction mode 2)
Sample Containers	• 16 × 100 mm tubes	• 20 × 150 mm tubes • 16 × 150 mm tubes • 16 × 100 mm tubes
Sample Confirmation	5-place and 4-place weighing (min. weight of 100 mg or 200 mg, respectively)	5-place and 4-place weighing (min. weight of 100 mg or 200 mg, respectively)
Sample Tracking	Linear barcode reader	Linear barcode reader

Extraction & Liquid Handling

Extraction Mode 1	Sonicator (with UV Temperature sensor)	Homogenizer (2k RPM – 20k RPM)
Extraction Mode 2	Vortexer	Vortexer
Extraction Volume	• 1 mL – 10 mL (16 x 100 mm test tube)	• 20 mL – 100 mL (extraction vessel), or • 50 mL – 520 mL (extraction vessel), or • 1 mL – 10 mL (16 x 100 mm test tube)
Filtration	Syringe	Fluid metering pump and syringe
Syringe-driven Liquid Dispensing	0.05 mL – 10 mL	0.05 mL – 10 mL
Max. Dilution Ratio	1:100,000	1:52,000,000
Max. Number of Solvents Connected	9 solvents	5 solvents

Analytical Finish

Off-Line	• Sample collection in test tube racks on APW platform • Sample collection into sealed vials in SAM	• Sample collection in test tube racks on TPW platform • Sample collection into sealed vials in SAM
HPLC On-Line	• HPLC fixed loop injector • incl. Waters Empower™ interface	• HPLC fixed loop injector • incl. Waters Empower™ interface
UV-Vis On-Line	Sample collection followed by automated transfer into UV-Vis	Sample collection followed by automated transfer into UV-Vis

Controls (Minimum Requirements)

PC	• Windows 7-64 bit • Dual Core Processor
Database	• MS SLQ Server 2000 or greater • Express, Workgroup or Standard Edition

Dimensions

APW / TPW Automated Sample Prep. Workstations	• Height: 42" / 107 cm (incl. Light Tower) • Width: 45.5" / 116 cm (with balance LCD panel) • Depth: 36" / 91 cm
SAM Sample Manager	• Height: 27.5" / 69 cm • Width: 21.5" / 55 cm • Depth: 30" / 76 cm

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
- First Line Responder training
- Preventive maintenance
- Technical support
- Repairs
- Updates, upgrades, and customization
- Compliance services (cGMP compliant qualification: IQ, OQ, PQ, 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 "fit for purpose" method 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 automated methods across sites
Method validation	Speed rollout by allowing us to facilitate and document validation of your method at your site
Application support at installation	Screen your applications for potential hurdles and prioritize methods to be automated to develop an efficient and effective 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 automation of your methods

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Z500-4002-02_V001-03/2014