Automated Sample Preparation

sotax

Why automate sample preparations?

For content and blend uniformity, potency, and related substances assay —

Sample preparation can be a very general term. When we talk about sample preparations at SOTAX, we are referring to the volumetric preparations of API, solid and liquid oral dosage forms, creams, and pastes. Automated Sample Preparation enhances laboratory productivity by minimizing resource allocation for repetitive tasks such as sample weighing, extraction, filtration, dilution, and transfer to analytical devices. This enables the re-purposing 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.

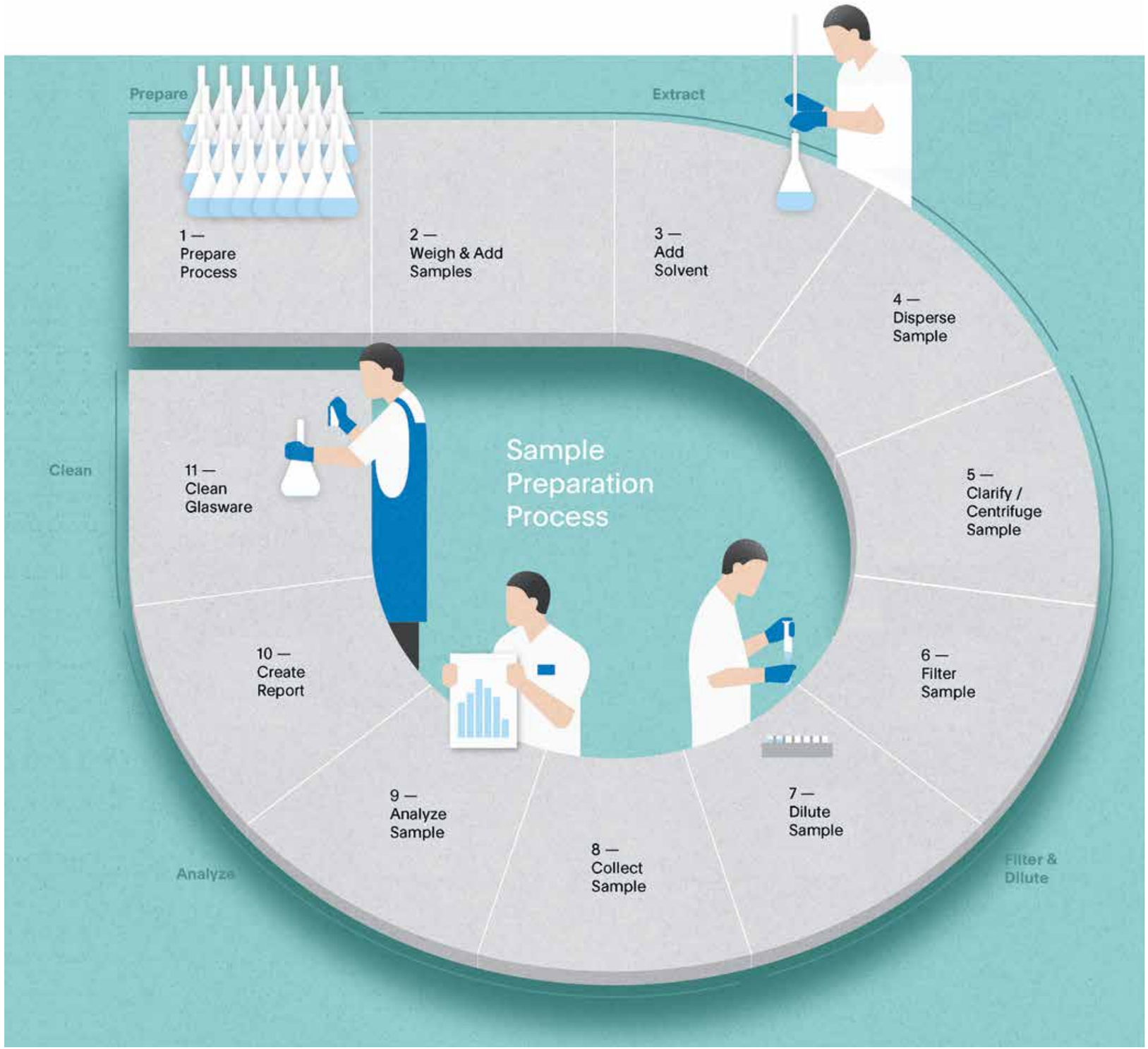
Why automate? — p. 1
Streamlined workflow — p. 4
APW & TPW — p. 9
Process steps — p. 12
Benefits — p. 14
Modules / SAM — p. 18
Modules / C+ — p. 20
Services — p. 23
SOTAX Group — p. 33

Automated Sample Preparation
for content and blend uniformity, potency,
and related substances assay

Streamline your laboratory workflow.

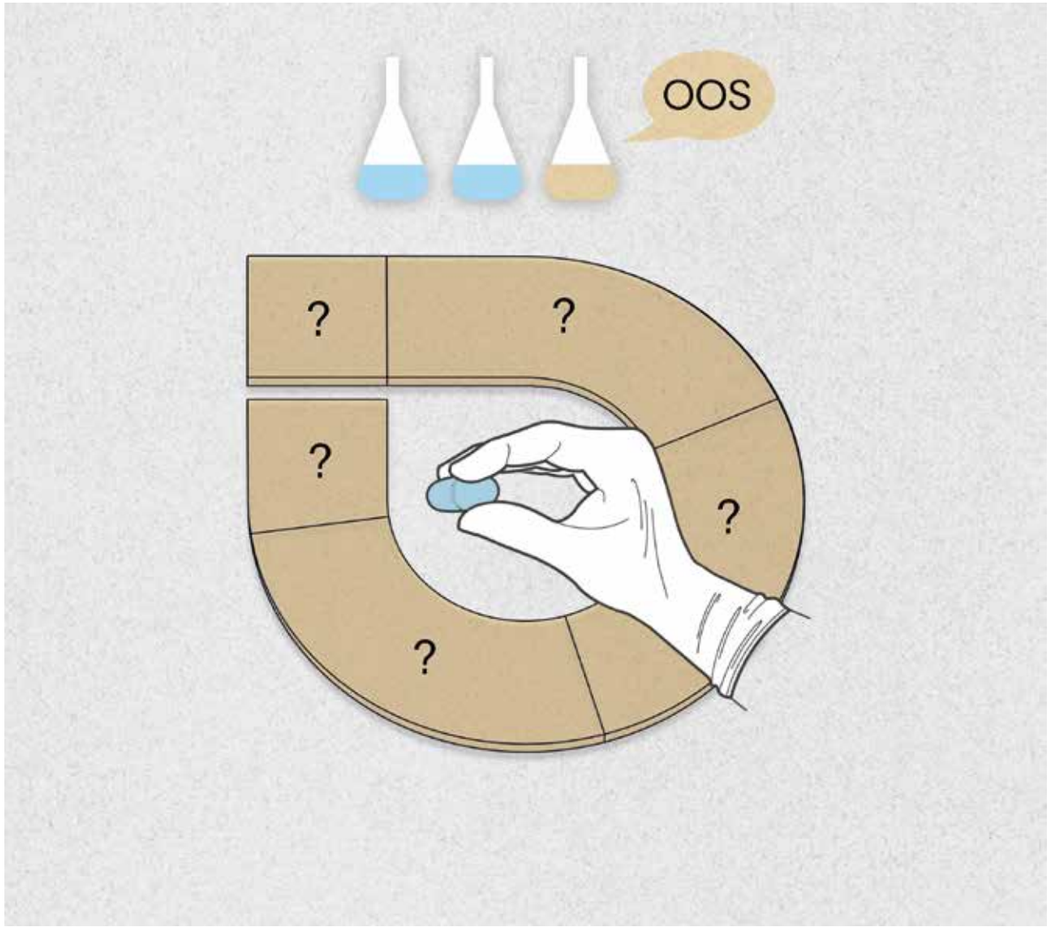
Automation facilitates processing labor-intensive samples for a broad spectrum of challenging formulations including tamper-resistant, osmotic pump, modified, extended, and delayed release. With robust focused extraction techniques the samples are consistently prepared across a variety of analysts and 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 data integrity principles into the drug product life-cycle 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 hundreds of installations globally, processing hundreds of thousands of samples, Automated Sample Preparation Systems have proven to be reliable and compliant solutions to enhance your laboratory's efficiency and accelerate the workflow.



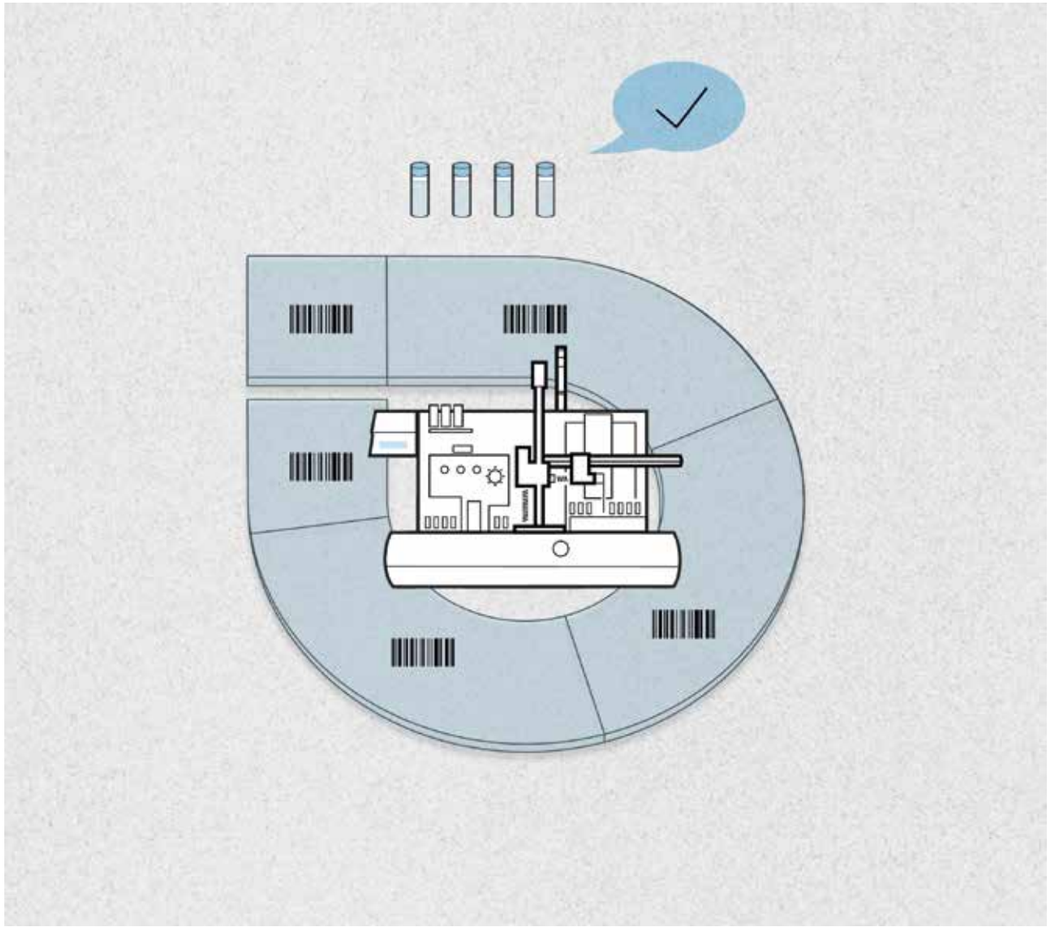
Manual —
out with the old...

Volumetric glassware has 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 errorprone 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, reduce solvent costs, and improve the data integrity of your samples.



Enhanced for greater productivity.

The APW and TPW Automated Sample Preparation Systems have been enhanced to provide even greater sample preparation productivity and reduced cycle time while streamlining your laboratory workflow. The APW and TPW work with 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 for an array of applications. From API to suspensions to tablets to medicated feeds, the APW and TPW provide a range of support from simple sample preparation to bar-coded sample ID and preparation with online HPLC analysis and compliant data transfer to your validated CDS.

APW & TPW — reproducible fit-for-purpose methods.

sotax.com/TPW

- For up to 300 samples
- Compliant automated preparation and analysis
- Built-in data integrity
- Waters Empower™ interface
- Simplified extraction of tamper-resistant or difficult ER and CR formulations

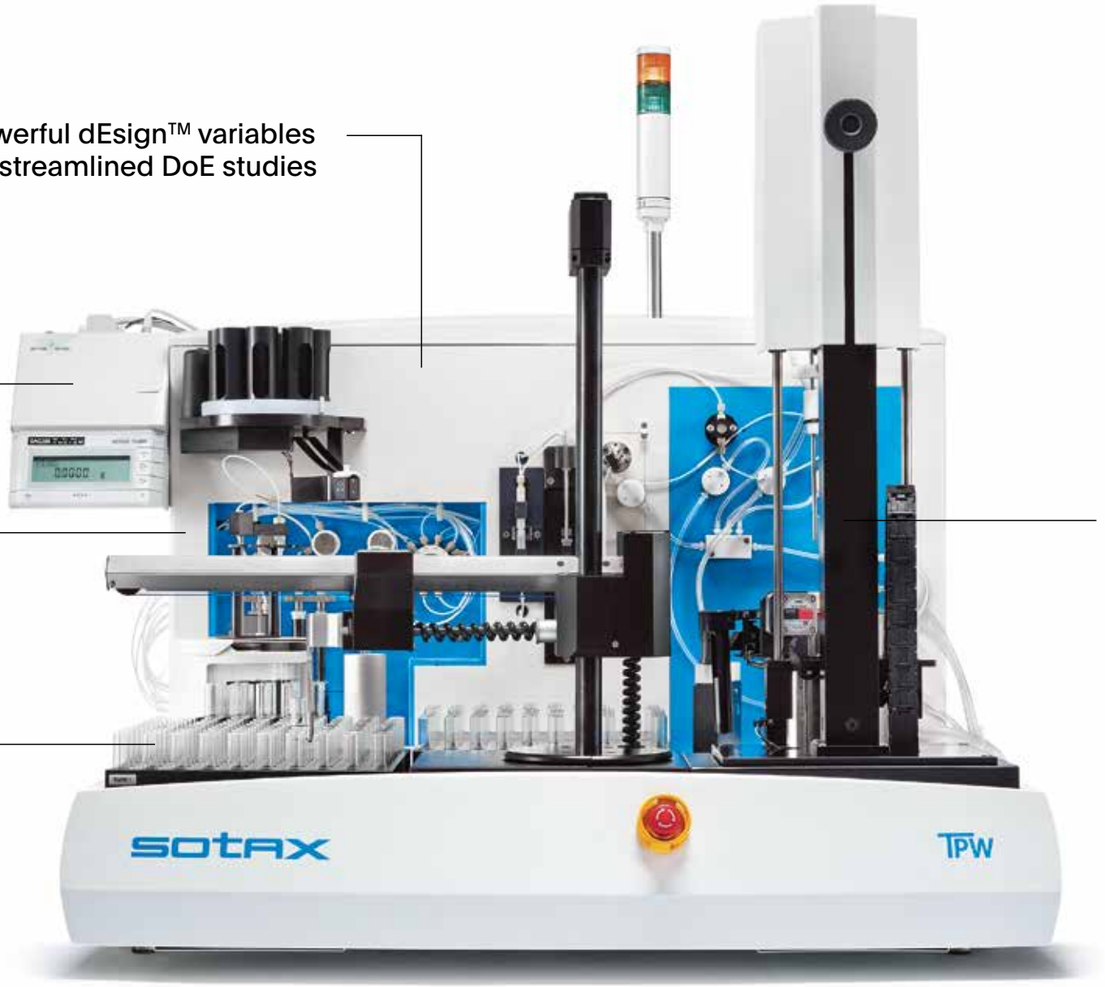
Powerful dEsign™ variables for streamlined DoE studies

Gravimetric confirmation of volumetric preparations at every step throughout the process

Up to 1:10’000 dilution ratio within a single method (post filtration)

TPW —
Assay and content & blend uniformity for up to 100 samples

APW —
Assay and content & blend uniformity for up to 300 samples



TPW —
20 – 520 mL initial extraction volume using a high-shear homogenizer

APW —
1 – 10 mL initial extraction volume using a focused sonication probe

Fully automated process steps.

Extract

The TPW uses a high-shear homogenizer to quickly extract samples. Alternately, the APW uses sonication coupled with a UV temperature sensor to deliver focused 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.

Filter & Dilute

The TPW filters extracted samples as they are transferred from the extraction vessel to test tubes. Post filtration, both systems can perform up to 1:10’000 dilutions ratio within a single method. 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 process.

Analyze & Store

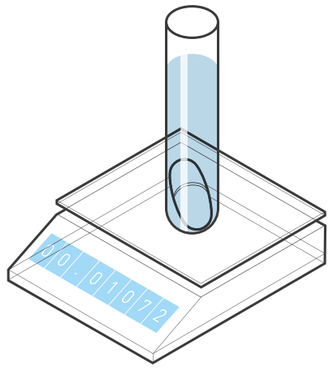
Both units support online HPLC analysis. A Waters Empower™ interface is also included to provide compliant data transfer to Empower™ for enhanced traceability. All result-critical information is transferred to Empower™ as the sample run-list progresses. Samples can also be collected in sealed HPLC vials to support various offline analyses.

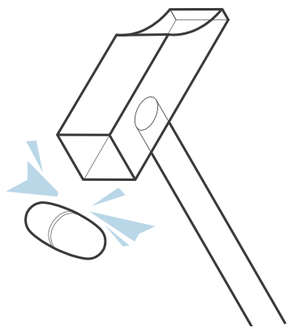
Benefits.

Perform high quality preparations

Automated Sample Preparation means robust and reproducible preparation that is equivalent or superior to your manual analytical procedures. 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

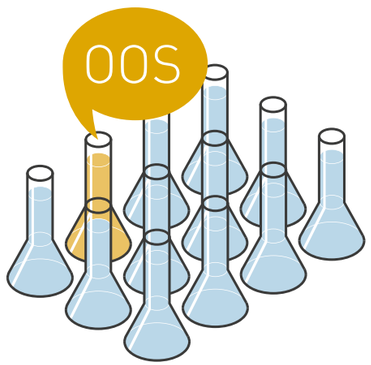
Products such as ER, CR, MR, osmotic pump, and tamper-resistant formulations present difficult challenges. This can result in increased method complexity and raise the risk of OOS results. Due to the physics of the focused homogenizer, the TPW is able to quickly break and extract even the most difficult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

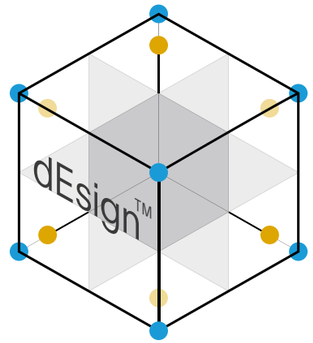
Break away from the limitations of shaking and stirring. Homogenization provides superior extraction for even the toughest jobs!

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 automation, each method step is gravimetrically confirmed and recorded in the secure database to ensure high quality results. The audit trail provides a compliant history of the entire process. In the event of an unexpected result, this audit trail ensures a well-defined assignment of root cause to simplify the laboratory investigation.

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 provides rapid assimilation of the 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). 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 life-cycle. These powerful software functions allow you to plan and execute method development DoE activities efficiently. The intuitive software interface streamlines the method transfer across sites.

DoE and data integrity for analytical methods are no longer just buzz words. TPW and APW are "designed for experiments"... Today.

APW & TPW Technical 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		APW 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 (2'000 rpm – 20'000 rpm)
	Extraction Mode 2	Vortexer	Vortexer
	Extraction Volume	1 mL – 10 mL (16 × 100 mm test tube)	20 mL – 100 mL (extraction vessel), or 50 mL – 520 mL (extraction vessel), or 1 mL – 10 mL (16 × 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	1:10'000	1:5'200'000
	Max. Number of Solvents Connected	9 solvents	5 solvents
Analytical Finish	Offline	• 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 Online	HPLC fixed loop injector incl. Waters Empower™ interface	HPLC fixed loop injector incl. Waters Empower™ interface
	UV-Vis Online	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	Windows 7-64 bit, Dual Core Processor
	Database	MS SLQ Server 2000 or greater Express, Workgroup, or Standard Edition	MS SLQ Server 2000 or greater Express, Workgroup, or Standard Edition
Power Supply		120 V or 240 V (±10 %) / 50 – 60 Hz / 800 VA	120 V or 240 V (±10 %) / 50 – 60 Hz / 800 VA
Weight	(Without Packaging)	125 kg / 275 lbs	127 kg / 280 lbs
Dimensions	Width	116 cm / 45.5 inch (with balance LCD panel)	116 cm / 45.5 inch (with balance LCD panel)
	Height	107 cm / 42 inch (incl. light tower)	107 cm / 42 inch (incl. light tower)
	Depth	91 cm / 36 inch	91 cm / 36 inch

Technical specifications are subject to change without prior notice. Products illustrated in this brochure may include options or modifications not fitted as standard. No liability for errors and omissions.

Modules

SAM
Sample Manager.

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

Universal and efficient sample management

The SAM sample manager automatically collects processed samples from the TPW. It can be used either as a simple fraction collector to collect and store samples in standardized vials, or as an advanced sample manager to add or replace media and/or inject samples in an LC or UV-Vis spectrophotometer. The autosampler also protects the samples from temperature and light degradation.

SAM Technical Specifications

No. of Channels		1
Capacity		1 rack, up to 120 samples
Rack Types		15 rows on 1 channel for vials (2 mL, 4 mL)
Sample Output		Side port (non-coring) vented needle; incl. needle wash
Features		Syringe pump, needle wash, injection valve
Interfaces		USB type B, 2 × CAN, 2 × D-sub
Optional		Cooling rack (flow through) for 2/4 mL vials
		Opaque cover for UV and light protection
Power Supply		100 – 240 V (±10 %) / 50 – 60 Hz
Weight	(Without Packaging)	29 kg / 63.9 lbs
Dimensions	Width	40 cm / 15.7 inch
	Height	60 cm / 23.6 inch
	Depth	80 cm / 31.5 inch

C+
Centrifuge Module.

TPW and APW Automated Sample Preparation Work Stations already include robust sample filtration capabilities. However, several sample preparation methods require centrifugation as primary mode for sample clarification, for example in Pharma, Food/Feed, Fine Chemical, and Cosmetics Industries.

Enhanced sample clarification

There are many cases where the addition of this step will help to solve the challenge of samples that require centrifugation or centrifugation followed by filtration. The new C+ addition is an automated centrifuge module providing enhanced sample clarification capabilities during fully automated sample preparations.

- Lotions, pastes, ointments
- Polymer-heavy tablet formulations
- Hormone formulations
- Food science applications
- Suspensions

C+ centrifuge addition

For challenging samples requiring centrifugation or centrifugation followed by filtration, the C+ addition provides enhanced sample clarification capabilities. Two additional modules, a service robot and a high quality Hettich centrifuge, automate the complete sample preparation process. The Hettich benchtop centrifuge is available as a standalone system or connected to the fully automated sample preparation systems. Combined with the C+, it will elegantly handle the entire centrifuge process including robotic transfer of tubes to and from TPW / APW, automated speed, time and temperature control, and automated tube “balancing” for uneven sample numbers / weight. The C+ can be ordered with all new TPW / APW systems and is an upgradable addition to existing units.

C+ Technical Specifications

C+ Configurations	With cooled centrifuge	Hettich centrifuge model ROTINA 380 R (refrigerated, -20 to +40 °C)
	With Non-cooled Centrifuge	Hettich centrifuge model ROTINA 380
Max. rpm (Speed)		5‘100 rpm
Centrifuge Design		Benchtop
Buckets		Designed for 16 × 100 TPW / APW tubes
Tubes & Capping		Nalgene Polypropylene: • Compatible with method, centrifuge, and TPW / APW • Capped Tubes
Interfaces		RS-232 serial
Power Supply		110 – 120 V or 230 – 240 V (±10 %) / 50 – 60 Hz / 750 VA
Weight	(Without Packaging)	81 kg / 178 lbs
Dimensions	Width	47 cm / 18.5 inch
	Height	48 cm / 18.8 inch
	Depth	58 cm / 22.8 inch

Services

Friendly and competent customer service is key to retaining you as a satisfied customer. Based on this basic premise, our service engineers and sales & service partners assist you throughout the life cycle of your instrumentation – wherever and whenever you need us. Since its foundation in 1973, SOTAX has continuously extended the range of available services and has become a preferred partner of leading pharmaceutical companies worldwide.

Services

From application support to qualification services and on-site assistance – SOTAX service is ready to go the extra mile. Wherever and whenever you need us.

Global Customer Services

Analytical Services.

From method development to stability studies and commercial batch release in a US-FDA-inspected, certified Pharmaceutical Establishment with GMP-compliant quality system – our analytical services are a one-stop solution for pharmaceutical companies. Based on decades of experience and unique application knowhow, our team of experts will find a solution for your specific challenge.

R&D Services

- API screening and characterization
- Feasibility studies
- Method development
- Method automation
- Method validation and re-validation
- Method transfer

Routine Analytical Services (GMP)

- QC analysis
- Stability studies
- Clinical and commercial batch release

GMP CERTIFIED FDA

Support Services

- Troubleshooting and investigations
- Training
- Consulting
- Audits

Instrument Services.

Friendly and competent local service is the cornerstone of our business. A global network of service engineers and certified SOTAX partners assists you throughout the life cycle of your instrumentation – from on-site installation, qualification, and training, to preventive maintenance, regular re-qualification, and uncomplicated troubleshooting support in case of problems.

Compliance Services

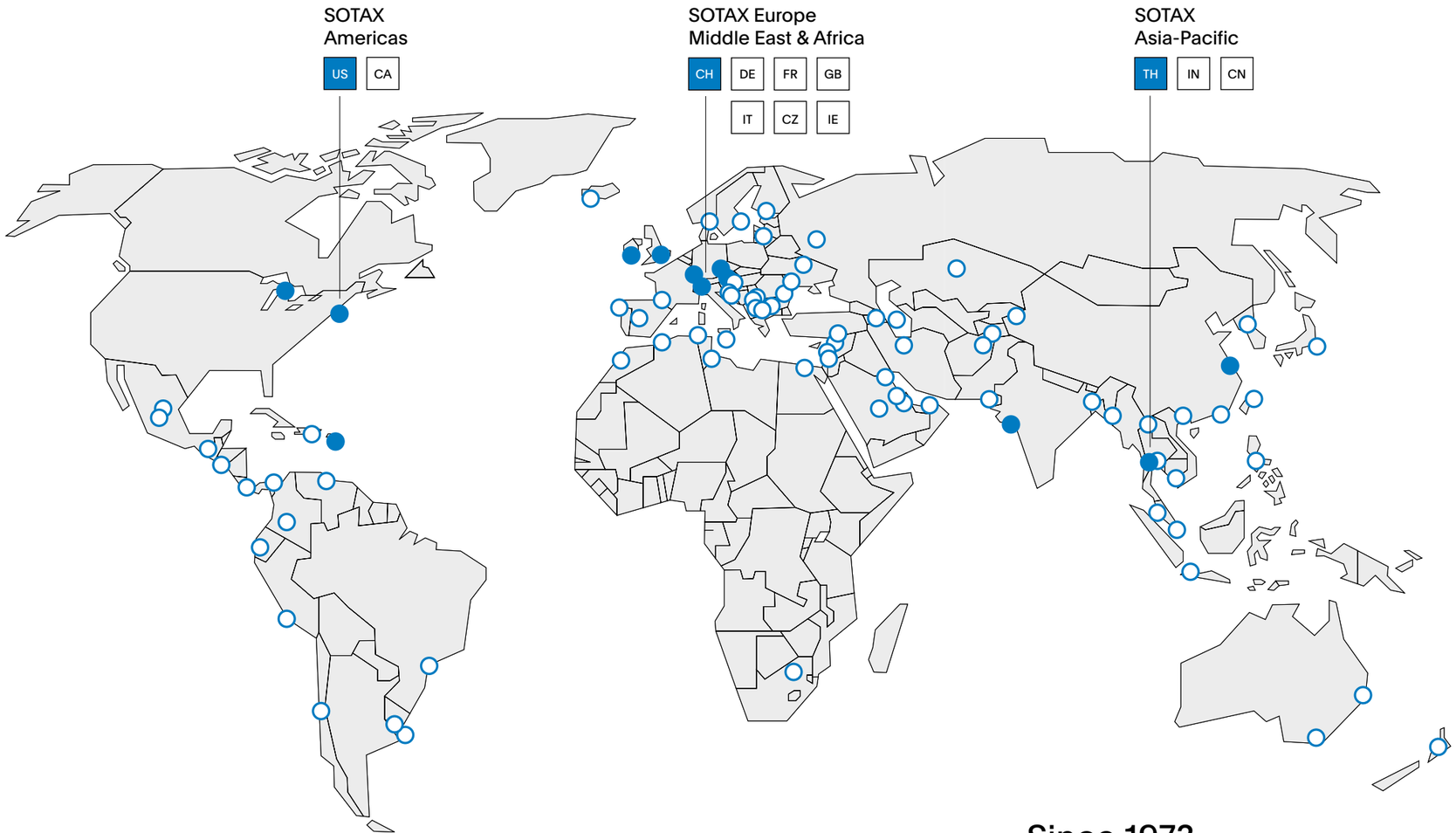
- Installation
- Qualification (IQ / OQ / PQ)
- PVT / ASTM
- Routine calibration and qualification
- Computer system validation (CSV)

Support Services

- Training
- Preventive maintenance
- Troubleshooting
- Repair
- Project management
- FAT / SAT
- LIMS integration
- Relocation services

sotax.com/services

We are there for you. Worldwide.



- SOTAX
- SOTAX Sales and Services Partner

Global network of trained and certified service engineers

Local presence in 90 countries

SOTAX companies in 12 countries

Largest service organization in our industry

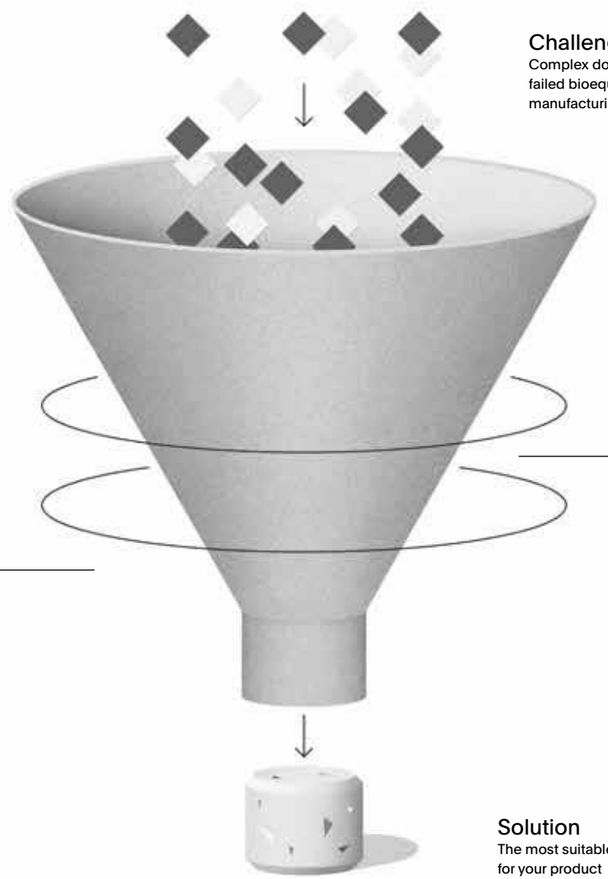
Since 1973.

SOTAX is built on services. Deeply rooted in more than 45 years of experience, we are specialists in what we do. Whether you need assistance with method transfer, require application support, or are looking for friendly, competent, and cost-effective qualification of your installed base – we are there for you. Throughout the life cycle of your products. Wherever you are.

sotax.com/worldwide

For Experts.
By Experts.

SOTAX offers unique specialist know-how in close cooperation with SPS Pharma Services. Set in an independent cGMP-compliant and FDA-inspected facility, a team of scientists, analysts, and lab assistants helps companies worldwide in overcoming the various challenges associated with release testing of pharmaceutical dosage forms.



Challenge
Complex dosage form, failed bioequivalence study, manufacturing issue

Know-how
Formulation properties, methods, analytics, instrumentation capabilities

Equipment
Dissolution
(USP 1 / 2 / 3 / 4 / 5 / 6 / 7)

Content testing
(uniformity, assay)

Automated platforms

Physical testing

Solution
The most suitable method for your product

SOTAX Customer Services

		Analytical Services	Instrument Services
R&D Services	API screening & characterization	●	–
	Feasibility studies	●	–
	Method development	●	–
	Method automation	●	–
	Method validation & re-validation	●	–
	Method transfer	●	–
Routine Analytical Services (GMP)	QC analysis	●	–
	Stability studies	●	–
	Clinical & Commercial batch release	●	–
Compliance Services	Installation	–	●
	Installation qualification (IQ)	–	●
	Operational qualification (OQ)	–	●
	Performance qualification (PQ)	–	●
	PVT / ASTM	–	●
	Computer system validation (CSV)	–	●
	Routine calibration	–	●
	Routine re-qualification	–	●
Support Services	Training (for different target groups)	●	●
	Acceptance tests (FAT / SAT)	–	●
	Project management	–	●
	Preventive maintenance	–	●
	Troubleshooting & investigations	●	●
	Repair	–	●
	Consulting	●	●
	LIMS integration	–	●
	Audits	●	–
	Relocation services	–	●

SOTAX Group

SOTAX Group

Reliable automation of simple laborious steps and finding innovative solutions for your testing problems has been our mission since 1973. From the world’s first flow-through dissolution tester to self-cleaning systems, patented tablet alignment, and user-friendly data management – SOTAX engineers specialize in making testing easier, faster, and more precise for you.

Knowing that there is more to a solution than innovative technology, we are proud to have the largest field service organization in our industry. Our global team of application experts, product specialists, and service engineers are looking forward to supporting you whenever you need it.

Whether you need help with an application problem or would like to learn more about possible efficiency gains in dissolution testing, physical testing, or automated sample preparation – SOTAX is your one-stop solution.

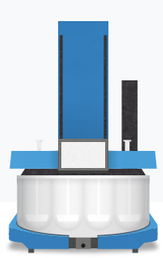
Product segments.

Data Management

Dissolution Testing

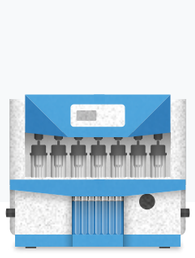
USP 1 / 2 / 5 / 6

- Manual
- Semi-Automated
- Fully Automated



USP 4

- Manual
- Semi-Automated



Automated Sample Preparation

Physical Testing

Hardness	Disintegration
Friability	Tapped Density
Flowability	Cap Torque
PAT	

Customer Services

Analytical Services

R&D Services	Routine Analytical Services (GMP)	Support Services

GMP CERTIFIED FDA

Instrument Services

Compliance Services	Support Services

Driving Innovation.
Milestones.

Foundation
SOTAX in Switzerland
(1973)

Flow-Through
Method
Integration in USP
(1991)

Foundation
SOTAX in USA
(1996)

Foundation
SPS Pharma Services
(2005)

Product Line
Content Testing
(2006)

Foundation
SOTAX in India
(2011)

Fully Automated Systems
ATF and AT50
(2018)

Acquisition
Labserv and GNA Analytical
(2019)

Product Line
Flow-Through Dissolution Tester
(1978)

Fully Automated Dissolution Tester
AT 700
(1993)

Product Line
Tablet Hardness Tester
(2002)

Acquisition
Zymark Automation
(2008)

Acquisition
Dr. Schleuniger® Pharmatron
(2013)

Product Line
Xtend™ Dissolution
(2014)

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
sotaxcz@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
Foston / Derbyshire
P Tech Support +41 61 487 5460
P Office +44 20 8349 6947
sotaxgb@sotax.com

Italy
Milan
P Tech Support +41 61 487 5460
P Office +39 02 8363 2641
sotaxitalia@sotax.com

Ireland
Longford
P Office +353 43 334 7779
contact@labserv.ie

Americas

USA (HQ Americas)
Westborough, MA
P Tech Support +1 508 544 4040
P Office +1 508 417 1112
sotaxusa@sotax.com

Canada
Westborough, MA
P Tech Support +1 508 544 4040
P Office +1 508 417 1112
sotaxcanada@sotax.com

Asia-Pacific

Thailand (HQ Asia-Pacific)
Bangkok
P Tech Support +91 99 202 11 211
P Office +66 26 42 68 62
sotaxasia@sotax.com

China
Shanghai
P Tech Support +41 61 487 5460
P Office +8621-6135 6268, ext. 205
sotaxchina@sotax.com

India
Mumbai
P Tech Support +91 99 202 11 211
P Office +91 22 4295 0191
sotaxindia@sotax.com

sotax.com

MB30005EN_01