



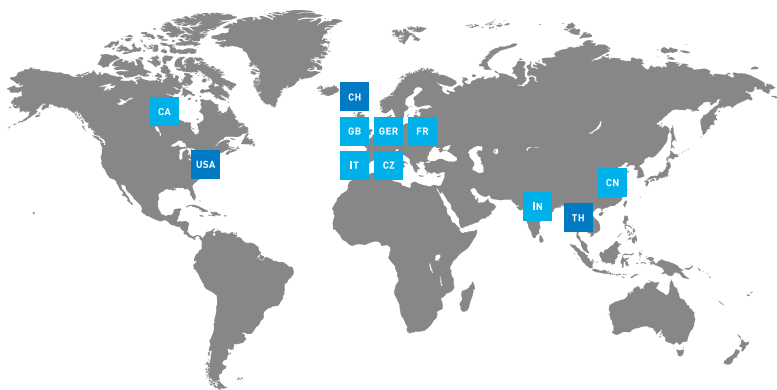
SDT

Off-line Dissolution System

- Swiss precision technology
- Compact footprint
- Round bath design for excellent visibility
- Simple EasyTouch™ operation
- 100% compliant with all Pharmacopeia

SOTAX

51798



■ Headquarters Business Unit

■ SOTAX Subsidiary

Wherever you are, whatever your target – we are side by side with our customers.

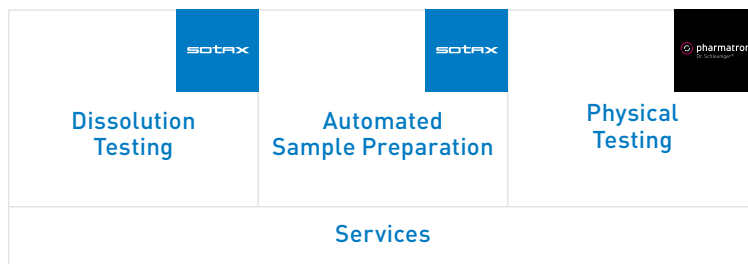
One of the pharmaceutical market's most valuable goals is to deliver affordable drugs faster to patients all over the world. In this effort the manufacturing processes in pharmaceutical industry are changing. Wherever you are, whatever your target, we are right by your side as a partner with global support: fast, local and reliable.

SOTAX worldwide – delivering customer confidence.

Customers globally rely on Swiss quality made by SOTAX. Most companies propagate the importance of customer service – but only few live up to this claim.

Built on the success of more than 40.000 systems installed and qualified internationally, our world-wide network of direct SOTAX sales and services as well as our long-time distributors are ready to go the extra mile for you – in more than 40 countries. As an expert in tablet release testing, SOTAX offers a wide range of premium

systems for dissolution testing, automated sample preparation, and physical testing. Innovative technology combined with in-depth application knowledge leads to uncompromised quality, reliability, and user-friendliness.



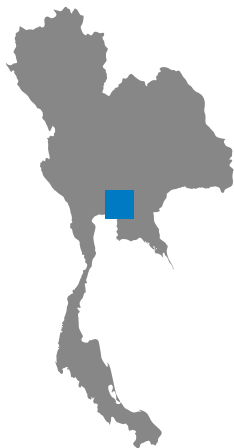
Innovation, equivalence, and harmonization

Under time-to-market pressure you develop your own products as an innovator or a CRO and submit them with their associated method to local or international regulation agencies for approval. You are then transferring the approved product and its methods from R&D to QC or CMO's. SOTAX helps you to get identical products and results during this whole scale-up process.

For generic products under high cost pressures you are looking for equivalence throughout the complete manufacturing process. Evaluating biowaiver possibilities will speed up your market introduction. SOTAX helps you in offering equivalent solutions adapted to your specific market needs.

Pushed by the worldwide harmonization effort, you are strengthening data security and validation procedures all over your company. SOTAX helps you by offering the same level of support and services worldwide – without compromising on quality and compliance.

SOTAX has been growing by understanding all these challenges decades after decades. As the leading company in pharmaceutical testing, SOTAX is your ideal partner for the future.



 SOTAX Asia Regional Office

Founded in 2017, SOTAX Asia Regional Office in Thailand is a 100% subsidiary of the SOTAX Group.

Our motivated team of highly experienced SOTAX sales and service engineers operates all across Asia.

40 years of experience paired with a close cooperation with scientific bodies (universities, SPDS-Society for Pharmaceutical Dissolution Science, IDMA, IPC, IPA, TIPA) enable us to bring a best-in-class dissolution experience to your lab.

Dissolution – tailored to our customers’ needs.

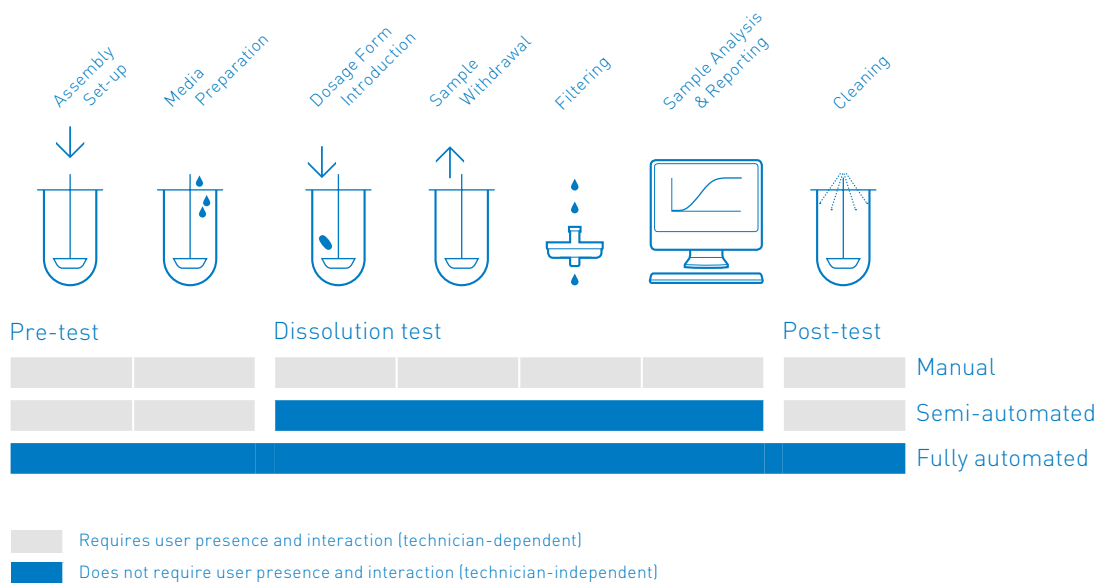
SOTAX solutions offer the ideal platform to meet all demanding workflows. Depending on your requirements, e.g. throughput, number of different products, or personnel availability, SOTAX offers a wide range of manual, semi-automated, and fully automated systems.

Based on market research and our local team’s experience, SOTAX has defined a semi-automated solution as the most appropriate system to meet fast emerging market requirements. The dissolution process can be separated into steps. Each of these steps can be executed in manual or automated mode. Manual steps are potential source of misinterpretation, transcription errors, delays, which can lead to OOS.

To face cost pressures combined with high quality and regulatory expectations, SOTAX has developed solutions to take away some of the most critical sources of failures such as sampling, filtering, collecting and documenting.

Our offline systems offer the ideal level of flexibility for UV and LC methods and opens the door for further automation.

Required Steps



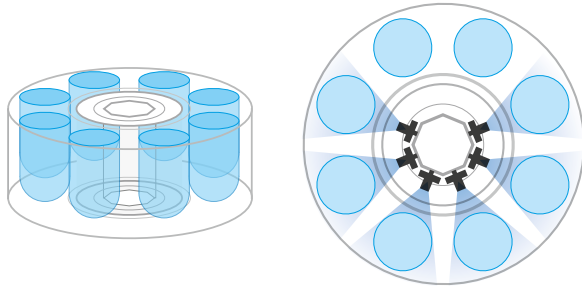
SDT Dissolution Apparatus

The SDT dissolution bath combines 40 years of experience with robust quality components, uncompromised usability, and state-of-the-art technology to guarantee reproducible testing conditions and compliance day after day.



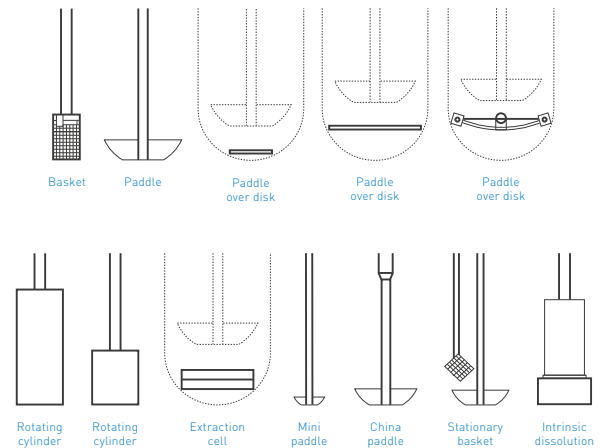
Perfect visibility

The round bath design of the SDT allows for easy observation of the dissolution process in each vessel at all times. Whether equipped with the optional CenterView™ video-monitoring or mirrored base plate, the SDT opens up a new dimension of observation possibilities for R&D visualization and OOS troubleshooting.



High flexibility

The SDT easily handles all USP 1, 2, 5, 6 methods with a great variety of different stirrer and vessel types. Depending on your needs, the SDT is available with 6–8 positions and is suitable for all dosage forms (e.g. tablets, capsules and sinkers).



Full compliance

Based on the SOTAX AutoCompliance™ concept with self-centering vessels, quick-lock system, and fixed shaft height – the SDT guarantees 100% compliance with all harmonized Pharmacopeia. Paddle, basket, vessel and shaft are serial number marked.



Easy operation

The SDT dissolution apparatus allows for fast and simple operation with the intuitive EasyTouch™ user interface. On top of that it also features easy set-up and method programming for manual or semi-automated test runs.



SFC Fraction Collector

The SFC is the ideal complement to the SDT dissolution bath offering high flexibility and accuracy in an integrated design. It allows sampling into LC vials and 12 mL tubes to adapt your sampling volume to your analytical needs.



Simple handling

All cleaning and handling processes are fast and simple to execute. Thanks to its compact design, the SDT off-line system makes it easier to prerinse and less prone to carryover.

Small tubing volume

SDT and SFC are installed next to each other. Since the syringes do not move, the tubing can be shorter there with reducing dead volume

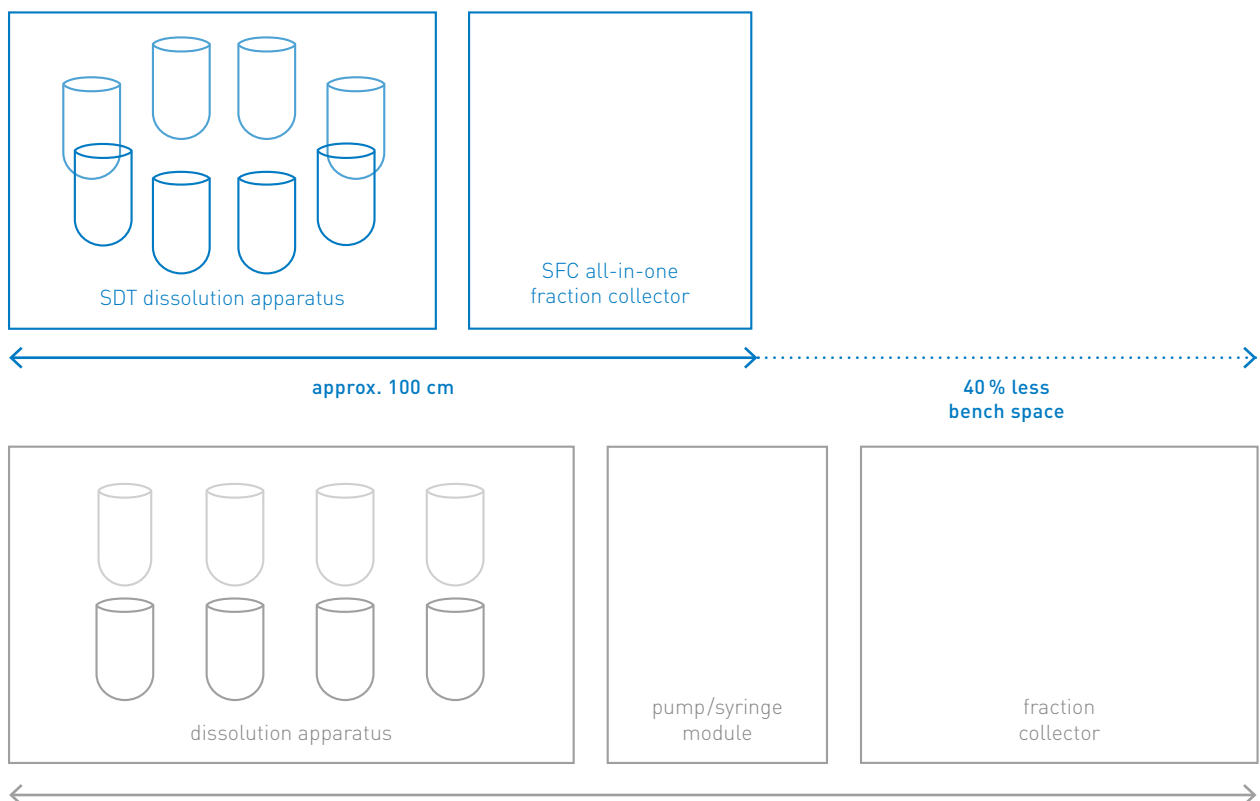
High accuracy

The integrated pump module uses high-precision 5 mL syringes and samples simultaneously through 6–8 channels – depending on your individual requirements. The sampling volume ranges from 1–10 mL with an accuracy of ± 0.5 mL or $\pm 10\%$.



Space-saving

The SDT off-line system with integrated SFC fraction collector has the smallest footprint in its class.





The SOTAX Group –
a global company with
strong local presence.

Service Competence

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.

Technical Service

Global, reliable, customer-focused. The SOTAX Global Service Network is available 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

Are you working on a new product and need data to support a new instrument acquisition – or maybe you are looking for assistance with automation implementation or method development but lack bandwidth?

Our team of experienced specialists can help you to save time and provide additional short-term capacity.

- Feasibility studies
- Method development
- Method transfer
- Application support
- Consulting
- Training and education

Service Contracts

Concentrate on your job – not on qualification deadlines and associated paperwork. Our service contracts provide trouble-free service and compliance coverage with cost assurance.

No surprises, no additional expense.

- Protect your capital investment
- Extend equipment life
- Receive priority service
- Scheduled routine service
- Cost assurance for the entire contract period

Technical Data



SDT Dissolution Apparatus

Methods	USP 1, 2, 5, 6	
Stirring positions	Number	6, 7, or 8
	Stirrer types	Various stirrer types available
	Stirring range	25 – 250 rpm
Vessels	Material	Glass or polycarbonate
	Types	Various vessel types available
Temperature range of bath	Room temperature +5 °C to 45 °C (± 0.1 °C)	
Memory	> 100 active methods stored in the memory	
Sampling	Pipette guides or AutoLift™ (cannulas)	
User Management	Password protection system	
Options	<ul style="list-style-type: none"> • Manual / Automatic bath opening mechanism • In-vessel temperature monitoring • Automatic tablet drop • CenterView™ video-monitoring 	
	Sampling	<ul style="list-style-type: none"> • Withdrawing with guided pipettes • Resident probes • AutoLift™
	Filtering	Filtering with pre-filter Cannula head or tip filters



SFC Fraction Collector

Channels	6, 7, or 8
Piercing	Yes
Racks	Vials (2 mL, 4 mL) Glass tubes (12 mL)
Syringe volume	5 mL
Media replacement	Yes
Control	EasyTouch™ (on the SDT)

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