

Convincing Solutions for your drug testing



► **Company**

SOTAX, founded in 1973, began as an engineering company to service the pharmaceutical and other industries. Today SOTAX is a leader in the development and manufacturing of test instruments and software for tablet testing and is a leading solution provider for the pharmaceutical industry. SOTAX is owned privately by the Benz family.

Worldwide, SOTAX has a staff of over 140 skilled and motivated employees. Its headquarter is in Allschwil, near Basel, the center of the pharmaceutical industry in Switzerland: manufacturing, engineering, research and development, as well as administration, sales and marketing departments are all located there together with a demo and application laboratory as well as an auditorium for conferences and seminars. SOTAX has sales and service organizations in Canada, China, France, Germany, Great Britain, Italy, Switzerland and the USA and is represented in other markets through local distributors. The US organization is located in Hopkinton, Massachusetts, with administration, demo and application laboratory, maintenance center and warehouse. SOTAX Corporation has a network of sales and service specialists throughout Canada and the USA.

SOTAX has established an excellent international reputation as a specialist in the development and production of sophisticated test equipment and automated systems. We work with major pharmaceutical companies to develop customized hardware/software solutions for their products. Our management focuses on very high quality standards in all operation levels and is continuously improving the quality of its systems to meet GMP, GAMP and ISO 9000-3 standards. In 1996 SOTAX received the ISO 9001 Certification, extended in 1999 to the TickIT Quality system for software development, thereby becoming the world's first supplier of dissolution testing systems to receive this seal of quality. SOTAX instruments meet all CP, EP, JP, USP and FDA Guidelines and SOTAX Softwares allow full compliance to 21 CFR part 11.

SOTAX also offers SPS Pharma Services (CRO), contract research lab dedicated to dissolution testing research, method development and advanced training. In 2008, SOTAX integrated the Zymark® automation product line, resources and services. With the addition of the Hopkinton facility in Massachusetts, customers benefit from SOTAX's increase US and global presence and network of direct sales and services.

SOTAX also offers its know-how as a service to the pharmaceutical industry, including installations, maintenance and repair services as well as a comprehensive and careful validation service in compliance with FDA regulations.

The loyalty displayed by our regular customers in more than 40 countries throughout the world encourages us to continue to deliver the highest quality.

▶ **Dissolution Testing**

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Features & Benefits

- ▶ Compliant with all Pharmacopeial methods including USP Apparatus 1 (basket), Apparatus 2 (paddle), Apparatus 5 (paddle over disk), Apparatus 6 (rotating cylinder), Intrinsic Dissolution, Stationary basket, and Mini Paddles/Baskets/Vessels
Fulfills all USP, EP, JP and CP requirements
- ▶ Seven vessels for 6 samples and 1 placebo or blank solution, staggered vessel design for unobstructed visual observation, built-in heater/circulator
Compact and space-saving design, vibration free, easy sample viewing
- ▶ Fixed position shaft height, automatic vessel centering and built-in evaporation covers
Fully conforms to ASTM Mechanical Calibration with low evaporative loss of media
- ▶ Program dissolution methods in firmware and print reports with built in printer report
Program assistance in tablet introduction, sampling times, protocol printout of test parameters incl. temperature, rpm, sampling times for traceability
- ▶ Tablet introduction assist
Simultaneous or staggered tablet introduction
- ▶ Serialized Shafts, Paddles, Baskets and Vessels with removeable bath and cover plate
Easy removal and cleaning of paddles, baskets, vessels and bath. Components identification for validation
- ▶ Modular concept ready for upgrades to automation with firmware or software control
Easy upgrades to automation with addition of autosampler, on-line HPLC, on-line UV-Vis spectrophotometer, UV Fiber Optics or Automated Sampling Device
- ▶ Sampling port on each vessel
Allows manual sampling through height adjustable cannula



Features & Benefits

- ▶ **Controlled by WinSOTAXplus Advanced Dissolution Software**
Allows full compliance to 21 CFR part 11 in standalone and client/server modes
- ▶ **Drivers available for several UV-Vis brands**
Possible use of existing UV-Vis spectrophotometers
- ▶ **Direct sample analysis during the test**
Dissolution curves available on the fly
- ▶ **Connect two baths to a single UV-Vis Spectrophotometer**
Enhanced productivity (12 samples)
- ▶ **Automatic sampling through or beside the shaft by Hollow Shaft™ or cannula**
Complete sampling reproducibility on the six samples and one placebo or blank solution
- ▶ **Simultaneous withdrawing, filtering and analyzing of the six samples and one placebo or blank solution**
Shortest measuring intervals for determining the release profile
- ▶ **pH change by Media addition and pH monitoring controlled by software**
Automate time consuming media changes
- ▶ **Compatibility with filter station FS 7**
Allows filter changes before each sampling time



Features & Benefits

- ▶ Automated sample injection or collection
Increased productivity
- ▶ Direct transfer of samples from dissolution bath to LC
Elimates manual handling errors
- ▶ Injections controlled by the external module
SOTAX MF 7-LC
Compatible with all major brands of HPLC
- ▶ Designed for rapid direct injection LC methods
Can be adapted to UPLC or equivalent systems
- ▶ Controlled by WinSOTAXplus Advanced Dissolution Software
Compatibility with other SOTAX Dissolution systems
- ▶ Automatic sampling through or beside the shaft by Hollow Shaft™ or cannula
Complete sampling reproducibility on the six samples and one placebo or blank solution



Features & Benefits

- ▶ Semi-automated system based on the AT 7smart, includes a pump CY7-50 and a fraction collector C613. Simultaneously withdrawing, filtering and collecting of the 6 samples and a placebo or a blank solution in open/capped LC vials or open glass tubes at each sampling time
- ▶ Firmware controlled with comprehensive menus or controlled by WinSOTAXplus Advanced Dissolution Software allowing compliance to 21 CFR part 11. System control flexibility
- ▶ Connect 2 baths to a single fraction collector. Enhanced Productivity (12 samples)
- ▶ Additional valve for media replacement. Sample volumes removed can be replaced by fresh solvent, allowing low volume dissolution profiles
- ▶ Automatic sampling through or beside the shaft by Hollow Shaft™ or cannula. Complete sampling reproducibility on the six samples and one placebo or blank solution
- ▶ pH change by Media addition and pH monitoring controlled by software. Automate time consuming media changes
- ▶ Compatibility with Filter Station FS 7. Allows filters change before each sampling time



▶ SOTAX AT 7smart Off-line

Automated sample collection for dissolution tests according to USP 1, 2, 5, 6 and intrinsic Dissolution

ASD SOTAX AT 7smart ASD

Features & Benefits

- ▶ Robotic system integrated with SOTAX AT 7smart
Compact space-saving system, upgrades any existing standard AT 7smart
- ▶ Sample collection into HPLC capped vials
No evaporation of the collected samples
- ▶ No system tubing volume
Avoids potential adsorption problems (e.g. adherent products such as hormones)
- ▶ Firmware controlled method programming and reporting
Easy programming



▶ **SOTAX AT 7smart ASD**

**The automatic staggered sampling system
for SOTAX AT 7smart**

Features & Benefits

- ▶ Simultaneous In-Situ UV-Vis measurements in 7 vessels
No tubing, no pumping, no filtering, no gap time, no dead volume
- ▶ Controlled by WinSOTAXplus Advanced Dissolution Software
Allows full compliance to 21 CFR part 11 in standalone and client/server modes
- ▶ Uses patented ARCH Probes™ and standard immersion probes
Low disturbance open design, prevents excipient buildup, bubble entrapment and provides consistent minimal path-length measurements
- ▶ CCD Detector optimized for fast UV readings
Real simultaneous measurements on 6 channels
- ▶ No sample removal, filtering or pumps
Minimal hydrodynamical effects with ARCH Probes™ with the possibility to run methods developed on standard probes
- ▶ In-Situ measurements
Amazing ability to scan simultaneously on 6 vessels



Features & Benefits

- ▶ Fully automated tablet dissolution system for a series of 10–15 dissolution tests using the USP 2 method
10 to 15 test without any user intervention
- ▶ Automates the entire dissolution test from media preparation and delivery, sampling, filtering, collection and/or analysis, and vessel cleaning
Method transfer from manual to automation with guaranteed reproducibility monitored on every step and complete traceability
- ▶ Controlled by WinSOTAXplus Advanced Dissolution Software
Immediate familiarity for WinSOTAXplus users, same drivers as for semi-automated systems
- ▶ Media change procedures allow additions, replacement or a full change of media
Allows difficult method transfers with pH monitoring and dispensed and added media volume validation
- ▶ Compatible with a variety of sinker types
Allows multiple capsule testing (R&D and QC)
- ▶ Specific solution for pellets and granulates
On-going development for specific USP 2 customers needs
- ▶ Worldwide Network of dedicated product specialists for support and validation
Complete validation IQ, OQ, PQ under Maintenance and Validation contracts



Features & Benefits

- ▶ The AT 70 BS 60 has all the features of the AT 70smart plus:
- ▶ Up to 10 dissolution tests for USP 1 methods
Maximum throughput on USP 1 and 2 methods
- ▶ Simultaneous attachment and removal of test baskets
Maximal productivity due to minimal inter-test time
- ▶ Optical sensor confirmation of basket attachment and removal
Accurate and reproducible automation process checking potential errors
- ▶ Short and thorough cleaning cycle for tubes, baskets and vessels
Complete cleaning of the systems (tubes, baskets, vessels)
- ▶ Specific solution for sticky products
Unique custom solutions for specific USP 1 methods

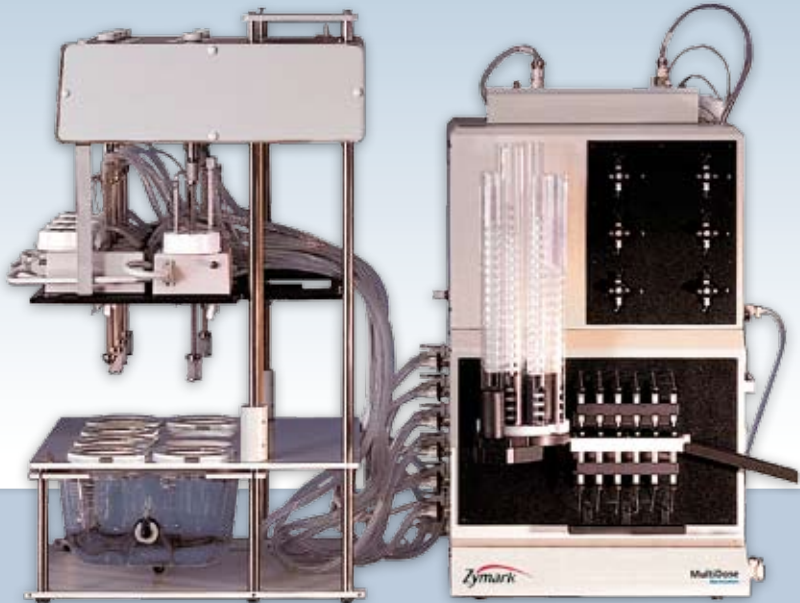


MDG3 Zymark® MultiDose G3



Features & Benefits

- ▶ Automate some existing manual dissolution baths
Simplifies tedious method transfers from manual to automation
- ▶ Eight different basket or paddle methods with different requirements within each batch
Flexible open architecture allows for a wide variety of applications
- ▶ Compatible with a wide range of sinkers including Japanese sinkers
Easy method transfer from manual to automation even for methods with sinkers
- ▶ Gravimetric recording of initial vessel volume prior to running method
Increased traceability compared to equivalent manual methods
- ▶ Probe equipped with temperature sensors to measure and record in each vessel at each sampling point
Improved efficiency in development compared to equivalent manual bath methods



▶ **Zymark MultiDose G3**

**Proven MultiDose® and MultiDose Plus®
for fully automated dissolution analysis
for paddle and baskets**

Features & Benefits

- ▶ Dissolution media preparation with a mobile space saving unit
Can be moved close to the Dissolution bath location to avoid any vessel or bath displacement
- ▶ Use of concentrates with on-line preparation or by sequential addition
Time and money savings
- ▶ Automates heating, stirring and vacuum degassing of the dissolution media
Improves reproducibility and reliability
- ▶ Volumetric filling at 1500 ml/min with an accuracy better than 1 %
Fast and accurate volume dispensing without glassware
- ▶ Gravimetric self-calibration option with built-in balance and printer port (optional)
Print out volumes dispensed and Calibration reports
- ▶ Optional tray for media tank holding, protection bars
Simplified handling of media tanks



Features & Benefits

- ▶ Automates 25 mm luer-lock filter changes after each sampling point
Solves saturation and clogging problems
- ▶ Filter change controlled by AT 7smart firmware or by WinSOTAXplus Advanced Dissolution Software
Complete extended and modified release testing and media change methods automation
- ▶ Allows the use of 0.45 micron porosity 25 mm filters (with the SOTAX CP 7 pump)
Complete the SOTAX fraction collector with filtered samples ready for HPLC analysis
- ▶ Uses SOTAX and Zymark certified Pall™ PSF filters
Simplifies filter validations and method transfers to full automation
- ▶ Compatible with AT 7smart On/Off-line systems
Upgrade easily the existing SOTAX semi-automated systems On and Off-line
- ▶ Storage up to 140 filters and collection tray for dispensed used filters
Easy filter handling



▶ SOTAX FS 7

The SOTAX FS 7 Filter Station for reliable automated filter changes after sampling in semi-automated dissolution systems

Features & Benefits

- ▶ Flow-through cell (Apparatus 4) instrument with pump and UV-Vis spectrophotometer
Designed for semi-automatic USP 4 methods with photometric analysis
- ▶ Cells available for tablets, capsules, powders, APIs, lipophilic forms, suppositories, suspensions, liposomes, microspheres, semi-solids, implants and medical devices
Testing of several dosage forms, including novel dosage forms, in dedicated cells
- ▶ Available in closed and open loop configurations
Useful for low dose and poorly soluble formulations
- ▶ Controlled by WinSOTAXplus Advanced Dissolution Software
Allows full compliance to 21 CFR part 11 in standalone and client/server modes
- ▶ Drivers available for several UV-Vis brands
Possible use of existing UV-Vis spectrophotometers
- ▶ Direct sample analysis during the test
Dissolution curves available on the fly





SOTAX CE 7smart Off-line open system

Features & Benefits

- ▶ Flow-Through Cell (Apparatus 4) instrument with pump and fraction collector
Designed for semi-automated USP 4 methods in open loop
- ▶ Cells available for tablets, capsules, powders, APIs, lipophilic forms, suppositories, suspensions, liposomes, microspheres, semi-solids, implants and medical devices
Testing of several dosage forms, including novel dosage forms, in dedicated cells
- ▶ Automated media change with media selector
Recommended configuration for media and/or pH changes
- ▶ Continuous pumping of fresh media with on-line degassing option
Ideal for dissolution testing of poorly soluble compounds
- ▶ Automated fraction collection
Flexible sample collection from minutes to months
- ▶ Controlled by WinSOTAXplus Advanced Dissolution Software or by firmware
Allows full compliance to 21 CFR part 11 in standalone and client/server modes



▶ **SOTAX CE 7smart
Off-line open system**

**Open loop off-line with fraction collector
for dissolution tests according to the Flow-
through Method (USP 4)**

Features & Benefits

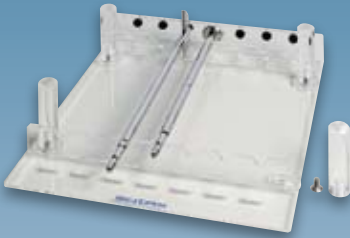
- ▶ Flow-through Cell (Apparatus 4) instrument with pump and fraction collector including a syringe autosampler
Designed for semi-automated USP 4 methods in closed loop with low volume sampling (e.g. Medical Devices and Drug Eluting Stents Elution methods)
- ▶ Cells available for tablets, capsules, powders, APIs, lipophilic forms, suppositories, suspensions, liposomes, microspheres, semi-solids, implants and medical devices
Testing of several dosage forms, including novel dosage forms, in dedicated cells
- ▶ Ideal for small media volume testing
Ideal system for Stents and Medical Devices Elution testing
- ▶ Sample collection in closed HPLC vials or test tubes with up to 29 rows
Allows small volumes sampling during long term testing down to 100 µl or micro liters
- ▶ Controlled by CE 7smart firmware
Password protected methods and printed reports
- ▶ Built in Needle rinsing system
Carry-over prevention



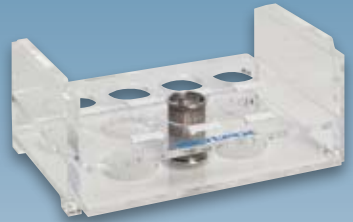
▶ **SOTAX CE 7smart**
Off-line closed system

**Closed loop off-line with syringe
autosampler for dissolution tests according
to the Flow-through Method (USP 4)**

SOTAX Dissolution Accessories



▶ Paddle and Basket Shaft Holder



▶ Rack for Baskets



▶ USP 4 Cell Holder Storage Tray



▶ Media Addition Valve Support



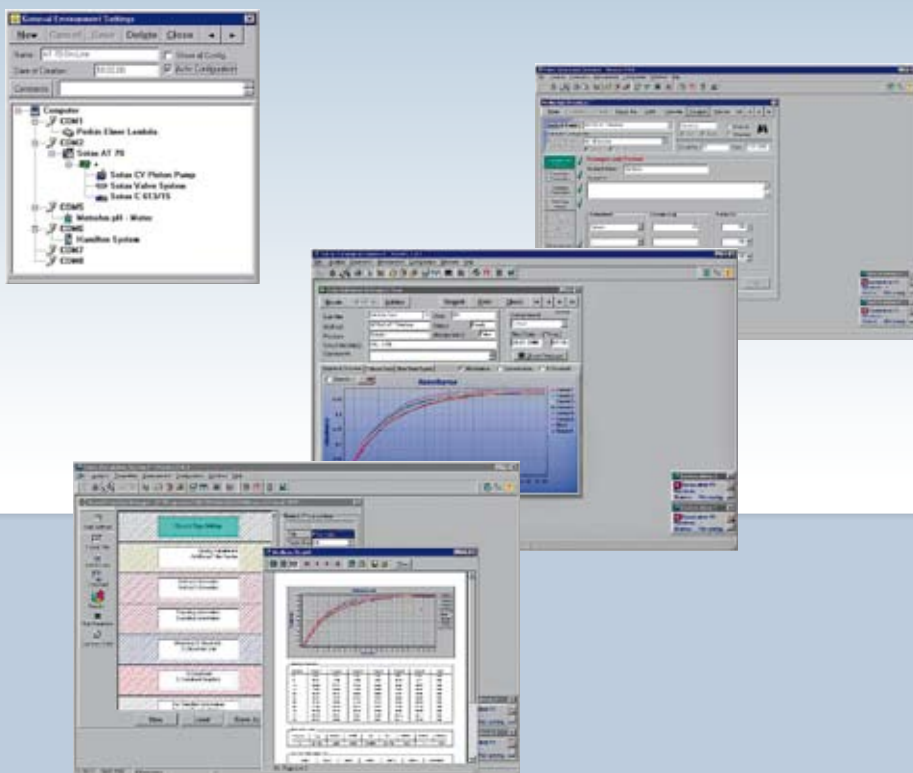
▶ Vessel cover



▶ Shaft Cleaning Assembly

Features & Benefits

- ▶ One unified software version for all SOTAX Dissolution semi-automated and fully automated systems
Faster Validation training for existing users, quick method transfer from semi-automation to fully-automation
- ▶ Microsoft SQL server Database
Scalable from a single workstation to a lab/ department/company network
- ▶ Validated software with configurable users rights and audit trails, protected database, log files
Allows compliance to GxP and 21 CFR part 11
- ▶ Dissolution Methods linked to System configurations
Users only see menus and dialogs which conform to their hardware configuration and user rights
- ▶ On-line modules for UV-Vis measurements with full scanning for diode array spectrophotometers
Dissolution data fully available on a single window during the test
- ▶ Various Calibration modes and protocoling of parameters
Configurable reports including instrument serial numbers, raw data, concentration and % dissolved, rpm, temperature, calibration data, signatures
- ▶ Export functionalities
Interfaces with LIMS and external softwares/databases/programs



▶ **WinSOTAXplus**
Advanced Dissolution Software

The most advanced Dissolution software controlling all SOTAX Dissolution system components in single workstation or in client/server modes

APW3 Zymark® APW3

Zymark

Features & Benefits

- ▶ Sample Preparation Workstation designed for Active Pharmaceutical Ingredients (APIs) Assays
Fully automated analysis for API stability Indicating Assays and Related Compounds
- ▶ Capacity for up to 300 samples
300 samples or 150 with a single step dilution can be run unattended
- ▶ Dual range four to five-place balance
Gravimetric confirmation assures liquid are dispensed with accuracy and precision
- ▶ Dispersing volume from 0.5 to 10 mL in 16 x 100 mm tubes
Versatility in applications: API, cleaning validation, low dose or soluble dose assay and uniformity
- ▶ Sonicating probe with temperature control (optional)
Increases the speed of sample extraction with sonication
- ▶ Sample Analysis by UV or LC. Waters Empower 2 Interface available
State of the art analytical integration: archive Samples in Capped HPLC Vials, optional Barcode Reader



▶ Zymark APW 3

The perfect tool for API
Stability Indicating and
other Assays



Features & Benefits

- ▶ Fully automated sample preparation workstation for tablets, capsules, powders and suspensions
Unattended operation. Fully automated analysis
- ▶ Automate from 50 to 200 samples without operator intervention
Method Development flexibility
- ▶ Dispensing volume from 50 to 500 µL. Low dose option from 20 to 100 µL
Improve robustness of sample preparation methods
- ▶ Dual range four to five-place balance, three place balance for dispersant solvent
Gravimetric confirmation assures liquids are dispensed with accuracy and precision
- ▶ Network capability
Save analyst time for added value tasks
- ▶ Sample Analysis by UV or LC. Waters Empower 2 Interface available
State of the art analytical integration: archive Samples in Capped HPLC Vials, optional Barcode Reader



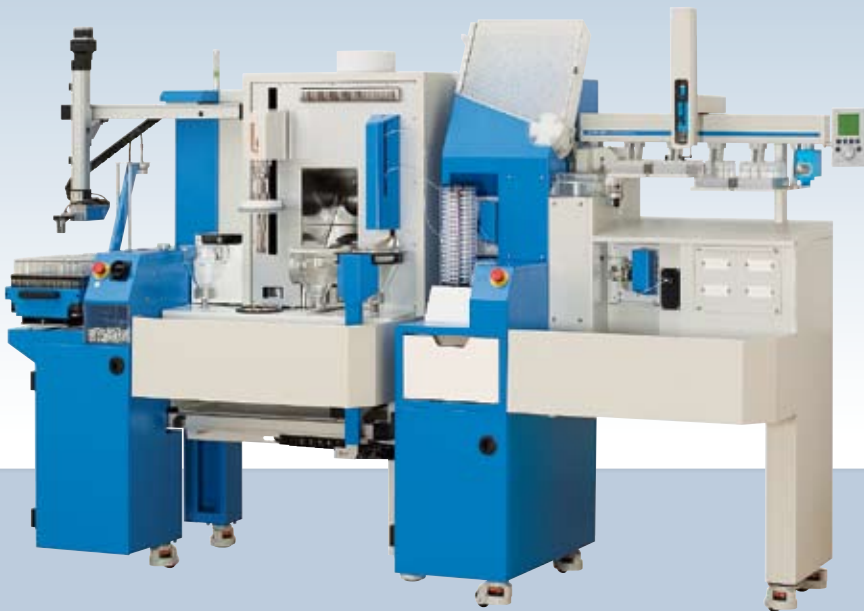
▶ Zymark TPW 3

Proven third generation TPW 3 Tablet Processing Workstation for automated content uniformity and assay testing

Features & Benefits

- ▶ Simultaneous sample processing
Increased sample throughput and speed of analysis for improved productivity
- ▶ Sample capacity independent from dilution steps:
up to 240 samples in 16 x 160 mm tubes or up to 80 samples in 32 x 115 mm tubes
Great flexibility and throughput for the introduction of a wide sample range (tablets, capsules, powder, pellets, liquids, Blend uniformity and effervescent tablet)
- ▶ Unique vessel design
Solvent volumes from 25 to 1000 mL
- ▶ 8-channel Solvent Selector
Allows complex methods automation
- ▶ Built-in ambient temperature sensor
Solvent dispensing based on density
- ▶ Brushless homogenizer motor
Maintenance free
- ▶ Unique cleaning design
Minimal solvent consumption, elimination of carry-over
- ▶ Off-line sampling with cooling option and injection in UV-Vis or in up to two LC systems
Complete flexibility in samples handling and analyzing
- ▶ Fully controlled by highly secured CT Software including user rights, electronic signatures audit trails
Allows 21 CFR part 11 compliance and paperless reporting





► **SOTAX CTS**

**High sample throughput for
automated content uniformity
and assay testing**

Features & Benefits

- ▶ Disintegration time testing unit with two basket-rack assemblies
Allows 3, 6 and 12 sample methods
- ▶ Each basket-rack assembly can be controlled, started and stopped individually
Individual measurement and reported value for each sample
- ▶ Automatically lowers the baskets at test start and raises the baskets at test end
Simplifies basket handling
- ▶ Optional automated detection of disintegration end point
Reproducible results in all media without any interpretation mistake
- ▶ Conforms to the latest USP <701> and <2040> chapters for disintegration testing
Fully compliant in manual and automated modes
- ▶ Connection to printer
Report printout with test results, statistics and temperature protocol
- ▶ Optional Q-Doc Prolab® quality documentation software
Allows 21 CFR part 11 compliance, paperless reporting and LIMS connection



Features & Benefits

- ▶ Two hardness measurement principles "Constant Speed" or "Constant Force" with a measuring range of up to 500 or 1000 N
Can be parametered to match existing tablet testers
- ▶ Equipped with the Auto Alignment™ device
Even the most difficult of tablet shapes are automatically aligned correctly to prevent erroneous hardness measurements
- ▶ Testing of hardness, thickness, width, diameter or length and weight (with a balance)
Testing of five essential physical parameters with results (in Newton, Strong Cobb or Kilopond; mm or inch; mg or g) and statistical data on display which can be printed out on a standard or label printer
- ▶ Operating conditions are programmable via front keypad with graphic display
The program menu allows the user to set specifications for the tablets as T1/T2/T3
- ▶ Optional Q-Doc Prolab® quality documentation software
Allows 21 CFR part 11 compliance, paperless reporting and LIMS connection
- ▶ Simplified calibration with the SOTAX Automated Dynamic Calibration Tool
No weights to carry
- ▶ Three point calibration and tablet orientation
Complies with <USP 1217> and EP 2.9.8



▶ **SOTAX HT 1**
Manual Tablet Testing System

The manual tablet testing system for fast, accurate and trouble-free measurements of all tablet shapes and sizes

Features & Benefits

- ▶ Two hardness measurement principles "Constant Speed" or "Constant Force" with a measuring range of up to 500 or 1000 N
Can be parametered to match existing tablet testers
- ▶ Tablet Feeder in teflon with engraved numbers
Easy to load, remove and clean
- ▶ Four-station transporter including self-cleaning brushes
Accurate automated testing on 20 tablets
- ▶ Equipped with the Auto Alignment™ device
Even the most difficult of tablet shapes are automatically aligned correctly to prevent erroneous hardness measurements
- ▶ Testing of hardness, thickness, width, diameter or length and weight (with a balance)
Testing of five essential physical parameters with results (in Newton, Strong Cobb or Kilopond; mm or inch; mg or g) and statistical data on display which can be printed out on a standard or label printer
- ▶ Operating conditions are programmable via front keypad with graphic display
The program menu allows the user to set specifications for the tablets as T1/T2/T3
- ▶ Optional Q-Doc Prolab® quality documentation software
Allows 21 CFR part 11 compliance, paperless reporting and LIMS connection
- ▶ Simplified calibration with the SOTAX Automated Dynamic Calibration Tool
No weights to carry
- ▶ Three point calibration and tablet orientation
Complies with <USP 1217> and EP 2.9.8



▶ **SOTAX HT 10
Semi-Automated
Testing System**

**The automated tablet testing system for
fast, accurate and trouble-free measurements
of all tablet shapes and sizes**

Features & Benefits

- ▶ Two hardness measurement principles “Constant Speed” or “Constant Force” with a measuring range of up to 500 or 1000 N
Can be parametered to match existing tablet testers
- ▶ The HT 100 has ten chambers with a capacity of 115 mL each (equivalent 200 medium-sized tablets)
Automated testing of 10 different batches of tablets, dragées, oblongs, effervescent tablets or similar drug delivery systems
- ▶ Vibration-free Auto Separator
Separates all shapes and sizes of tablets without manual adjustment
- ▶ Equipped with the Auto Alignment™ device
Even the most difficult of tablet shapes are automatically aligned correctly to prevent erroneous hardness measurements
- ▶ Testing of hardness, thickness, width, diameter or length and weight (with a balance)
Testing of five essential physical parameters with results (in Newton, Strong Cobb or Kilopond; mm or inch; mg or g) and statistical data on display which can be printed out on a standard or label printer
- ▶ Q-Doc Prolab® quality documentation software
Allows 21 CFR part 11 compliance, paperless reporting and LIMS connection
- ▶ Simplified calibration with the SOTAX Automated Dynamic Calibration Tool
No weights to carry
- ▶ Three point calibration and tablet orientation
Complies with <USP 1217> and EP 2.9.8



▶ **SOTAX HT 100
Fully Automated
Testing System**

**The fastest automated tablet testing system for
fast, accurate and trouble-free measurements of
all tablet shapes and sizes batch after batch**

Features & Benefits

- ▶ Performs a variety of test conditions including mixing and vibration settings
Produces precise, fast and reproducible results on the flowability characteristics of blends, powders and granulates saving time and product
- ▶ Standardized test conditions
Ensure optimum correlation of processing condition and optimal tablet press settings
- ▶ Vibration and mixing steps pneumatically controlled
Operator-independent results, eliminating human error
- ▶ Q-Doc Prolab® quality documentation software
Allows 21 CFR part 11 compliance, paperless reporting and LIMS connection
- ▶ Includes a Mettler precision balance
Accuracy of measurements
- ▶ Calibration and Qualification procedure
Traceability of results

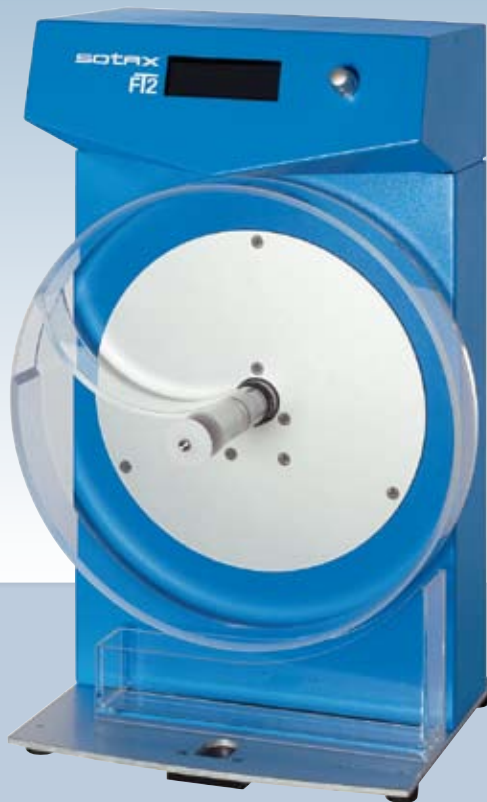


▶ **SOTAX FT 300**
Flowability Tester

To determine the flowability characteristics of blends, powders and granulates simulating processing conditions

Features & Benefits

- ▶ Front loading with built-in tilt
Easy to use with one or two drums
- ▶ Time, counter, speed modes
Flexible operation
- ▶ Easy to view LCD Display and scroll down menus
Designed for the user
- ▶ Calculation of percent friability and test report printed
As per GMP/GLP requirements
- ▶ Menu guided Qualification procedure
Easy Qualification
- ▶ Designed and manufactured in Switzerland
Accurate and robust



TD1 SOTAX TD 1 - Tap Density Tester

Features & Benefits

- ▶ One single position for all measurements
Compliance and simplicity
- ▶ Easy to view LCD Display and scroll down menus
Easy of use
- ▶ Calculation of results
Tapped Density, Compressibility Index and
Hausner ratio
- ▶ RS232 and Ethernet ports for
communication
Connection to a balance and print-out
of results
- ▶ Qualification procedure
Easy Qualification



▶ **SOTAX TD 1**
Tape Density Tester

**The most flexible Tap Density
Tester for EP, ASTM, USP I and
USP II tests**

Features & Benefits

- ▶ Automated control of the SOTAX family of hardness testers, disintegration, friability and powder flow testers
One single software for use with SOTAX physical testing instruments
- ▶ Laboratory Monitoring Software System (LMSS)
Connection to LIMS System
- ▶ Modular driver concept
Allows simplified integration of new components
- ▶ Microsoft SQL database
Full network capability
- ▶ Designed for the Pharmaceutical Industry
Allow compliance to 21 CFR part 11 and to GAMP 4



SOTAX Services



SOTAX, as a customer-oriented company, offers comprehensive after sales service covering installation, maintenance, qualification and repair. An extensive network of service engineers represents SOTAX all over the world. In addition to installation, maintenance and repair SOTAX also offers both operational and performance qualification services (OQ, MQ and PQ). Thoroughly trained SOTAX specialists qualify the units according to the cGMP and GAMP guidelines. These SOTAX Service Specialists help our customers on a daily basis maintaining their procedures, instruments and results in accordance to the latest Regulation Agencies guidelines.

► **Installation**

SOTAX includes system installation and training with all new purchases. We guarantee you that the instrument functions to specification and that its users are properly trained. SOTAX specialists install the systems including the control device and software in the SOTAX test laboratory prior to shipping to ensure correct functionality to specification. Upon delivery to the customer's laboratory the system is installed and again tested to specification prior to train its users. If the customer wishes, the required operational and / or performance qualification work can be performed by the SOTAX specialist.

► **Maintenance**

Though SOTAX test instruments are highly reliable and generally trouble-free, regular anticipated maintenance visits made by specialists are recommended. The FDA requires routine maintenance procedures for the test instruments for the development and quality control of the medicaments. If this is not sufficiently performed by laboratories, it can lead to non-conformance during an audit. SOTAX offers various maintenance solutions. Maintenance can be performed once or twice a year and can be written into a maintenance contract. The maintenance work performed is recorded and accepted by that company's responsible person and the laboratory is provided with all the necessary documentation in case of an inspection

► **Qualification**

SOTAX offers a calibration and qualification service in accordance with the USP, EP, FDA and GMP guidelines. This includes Design Qualification (DQ), Installation Qualification (IQ), Operational Qualification (OQ), Mechanical Qualification (MQ), each with the corresponding validation documents. In addition the required system suitability test or performance

qualification (PQ) using USP PVT tablets can be performed by our specialists. SOTAX actively participates in the USP multi-centre studies to determine the limits for these PVT lots and participates in the FDA collaborative studies. SOTAX qualification specialists continuously perform these PQ tests and are therefore the most experienced in their execution. Moreover, SOTAX bears the costs for repeating any PQ test that initially fails and therefore gives a supplementary qualification guarantee to the customer. SOTAX also performs MQ testing to the latest ASTM standards and service technicians are regularly trained to the latest MQ practices. These services are utilized by a wide variety of companies worldwide.

► **Repair**

If a SOTAX instrument becomes defective, our service technician can repair it on site or in the SOTAX repair center. SOTAX also offers maintenance and repair contracts to ensure maximum operational efficiency. Guaranteed reaction times keep fault-related interruption in use to an absolute minimum.

► **Contracts**

Full service, all maintenance, repair and qualification activities can be covered by a comprehensive service contract to secure operational readiness. Full service contract: guaranteed 72-hour reaction time with all services for restoring operational readiness in the event of a fault, yearly maintenance of the instrument on site and six-month OQ and PQ, incl. spare parts and travel expenses. Contact us at services@sotax.com to get your own contract.

Technical Hotline

Europe / Asia

Phone +41 61 487 5460
E-mail services@sotax.com

America

Toll Free +1 888 SOTAXUS
E-mail sotaxusa@sotax.com



Corporate Mission



▶ **Who we are and what we want**

SOTAX leads the way in the development and manufacture of high-quality pharmaceutical testing equipment and associated services. Our equipment is used worldwide in the development and production processes of our customers the pharmaceutical and science industries. SOTAX develops, produces and markets system solutions for pharmaceutical testing and does so in close cooperation with pharmaceutical and scientific partners. Our extensive market and process know-how enables us to meet our customers' requirements and comply with the key directives relevant to them. We are also open to cooperation with new industries. SOTAX is a leading independent company for pharmaceutical testing equipment. The company owes its independence to its sustained economic success. The SOTAX Group is a global success story and has subsidiaries around the world who are familiar with local needs and practices. We maintain our competitive edge by excelling in flexibility, performance, quality and safety.

▶ **Our customers**

The customer is in the centre of our activities. His satisfaction is our goal and quality standard. We set great store by efficiency and professionalism in meeting customer requirements. We also work with customers to turn visions for our business operations and future development into reality.

▶ **Our employees**

SOTAX values skilled, highly capable and enterprising staff who work for the greater good of the company, combining a sense of individual responsibility with team spirit. We also encourage creativity and personal skills through ongoing training.

Our employees cultivate a positive corporate culture through a friendly, open approach to both their fellow workers and our partners.

▶ **Our suppliers**

SOTAX sees its relationship with its suppliers as a partnership. Suppliers are expected to contribute to our joint success through their efficiency and professionalism.

▶ **Our environment**

We have a keen sense of our economic and social responsibility, and our actions, products and services make a significant contribution to protecting our environment.

Asia

- ▶ **SOTAX (Shanghai) Trading Company Ltd.**
800 Nanjing Road East
Room G, 15/F, No. 1 Plaza
CN-200001 Shanghai
Phone +86 21 6352 1008
Fax +86 21 6352 2213
E-mail sotaxchina@sotax.com

Austria and Switzerland

- ▶ **SOTAX AG**
Binnergerstrasse 106
CH-4123 Allschwil 1
Phone +41 61 487 5454
Fax +41 61 482 1331
E-mail info@sotax.com

Canada

- ▶ **SOTAX (Canada) Ltd.**
1-335 Deerpark Drive
CA-Brampton, ON L6T 5K3
Phone +1 905 494 0114
Toll Free +1 866 826 4448
Fax +1 905 494 0723
Toll Free +1 866 767 6077
E-mail sotaxcanada@sotax.com

France

- ▶ **SOTAX Sàrl.**
24, avenue de Bâle
FR-68300 Saint-Louis
Phone +33 3 8970 0846
Fax +33 3 8970 1781
E-mail info@sotax.com

France

- ▶ **SPS Pharma Services**
Bâtiment CBRV, 28 Place Henri Dunant
FR-63000 Clermont-Ferrand
Phone +33 4 73 17 83 98
Fax +33 4 73 17 83 99
E-mail contact@sps-pharma.com

Germany

- ▶ **SOTAX GmbH**
Wallbrunnstrasse 24
DE-79539 Lörrach
Phone +49 7621 16 5635
Fax +49 7621 16 5715
E-mail info@sotax.com

Great Britain

- ▶ **SOTAX Limited**
13 Station Road
GB-London N3 2SB
Phone +44 20 8349 6947
Fax +44 20 8349 6948
E-mail info@sotax.com

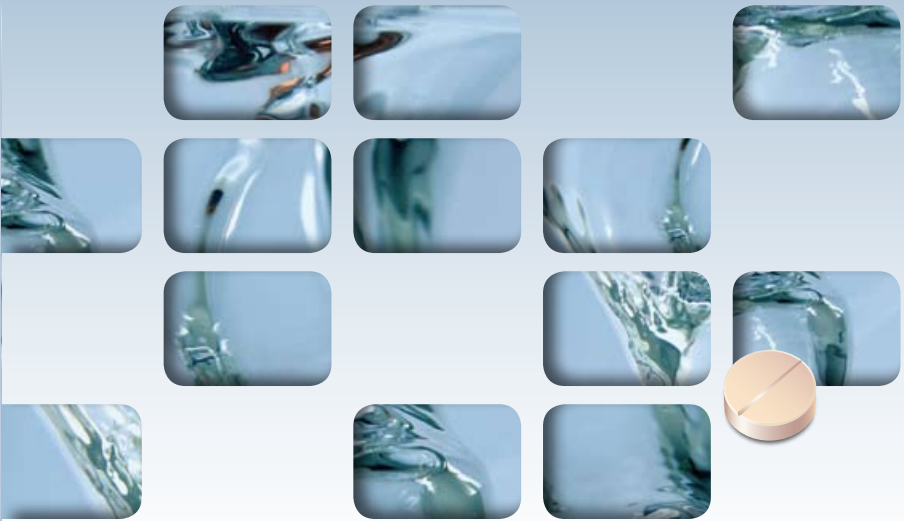
Italy

- ▶ **SOTAX S.r.l.**
Via Milazzo 14
IT-24124 Bergamo
Phone +39 035 21 9555
Fax +39 035 21 3643
E-mail sotaxitalia@sotax.com

USA

- ▶ **SOTAX Corporation**
68A Elm Street
Hopkinton, MA, USA
01748-1668
Phone +1 508 417 1112
Toll Free +1 888 SOTAXUS
Tech Support Hotline +1 508 544 4040
Fax +1 508 435 4691
E-mail sotaxusa@sotax.com

- ▶ **SOTAX Horsham**
411 Caredean Drive
Suite A
Horsham, PA 19044-1316



Technical Hotline

▶ **Europe / Asia**

Phone +41 61 487 5460

E-mail services@sotax.com

▶ **America**

Toll Free +1 888 SOTAXUS

E-mail sotaxusa@sotax.com

