

High productivity gain with AT 70smart

Test preparation and cleaning sequences are very quickly accomplished. Since the addition of test samples and removal of time-based samples occur simultaneously in all the test vessels, the system is substantially faster than other methods currently in use. A comparison shows that for 30-minute tests up to 20 tests per 24 hours are possible in an automated system using the AT 70smart. In a manual mode only four tests with a single bath can be executed.

No special expertise is required to run the system apart from knowledge of standard PC operations. Any additional information that is required is available through SOTAX training classes offered with the system installation.

System configurations

The SOTAX AT 70smart was developed to provide the most possibilities for user customization. But when needed, SOTAX enters into a fruitful collaboration with many users and customizes fully automated systems to their specific needs. Complex configurations are possible and can be easily designed to meet the specific requirements of your application.

On-line system with spectrophotometer

To ensure accurate and reliable on-line automation, the SOTAX AT 70smart is supplemented by the following components:

- SOTAX Piston Pump for adsorption-free tubing and pump components.
- A spectrophotometer with cell changer having at least 7 flow-through cells and RS-232 interface.
- WinSOTAX software driver for the spectrophotometer.

Off-line system with sample collection

For off-line automation, the SOTAX AT 70smart is supplemented by the following components:

- SOTAX CY 7-50 Piston Pump for adsorption-free pumping.
- SOTAX C 615 Fraction Collector with pneumatically operated valve block for filling up to 29 rows of 7 vials each with a different volume. Fraction collector racks are available for conventional HPLC vials.

On- and off-line

For maximum testing flexibility, a system with both on-line photometric analysis and off-line sample collection can be used. This system is especially beneficial for sample retention for photometric analysis, allowing for a sample to be taken at each measurement point, and is great for archiving. It also allows for flexibility between both HPLC and photometric methods.

On-line HPLC injection

The SOTAX AT 70smart can be supplemented with the following components for sample collection, processing, diluting and injections to the HPLC:

- The TS 70 transfer station
- The MS 70 multifunction interface

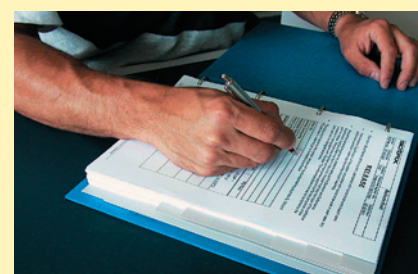
Validation and qualification

The SOTAX AT 70smart dissolution system has been developed according to ISO 9001-2000 quality standard and meets all requirements of the GAMP guidelines. The hardware as well as the system software have been validated and documented according to the latest quality guidelines (DQ). The appropriate qualification documentation (IQ/OQ) is supplied with each system. Documentation relating to the regularly recurring system calibrations is also provided.

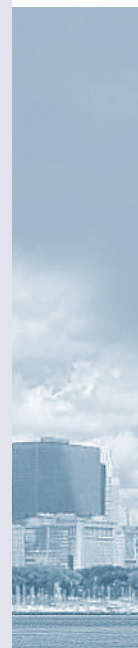
The system suitability test (PQ) with USP calibrator tablets can also be carried out by SOTAX staff.



Certificate



Complete validation documents



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Our design fits everywhere

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Fully Automated System with Basket Station BS 60



- Up to 15 unattended paddle dissolution tests (USP Apparatus 2) with the AT 70smart Paddle Station
- Up to 10 unattended basket dissolution tests (USP Apparatus 1) with the optional BS 60 Basket Station
- Automated media preparation and delivery from pre-made media or concentrate option with automated dilutions for up to 8 different media
- Tablet drop for a variety of tablet and capsule sizes including pellets and sinkers
- Unique vessel and system cleaning eliminates carryover from test to test
- Filter station uses a variety of market-available filters
- Hollow Shaft™ sampling system and Autocompliance™ provides reproducible results test after test
- Variety of analytical finishes available including on-line photometric analysis, off-line sample collection, on- and off-line capabilities, and direct injection into HPLC
- Optional pH monitoring, standard monitoring and virtual dilutions available
- Only system capable of media addition and complete media change methods
- Fully conforms to all USP and FIP guidelines
- Complete control via 21 CFR Part 11 compliant WinSOTAX Advanced Dissolution Software



Our design fits everywhere



The SOTAX AT 70 BS 60 for complete automation of USP 1 and USP 2 dissolution methods test after test



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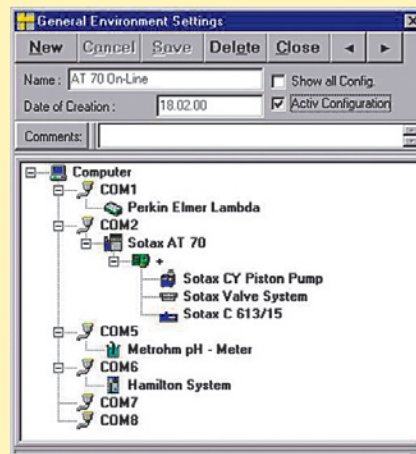
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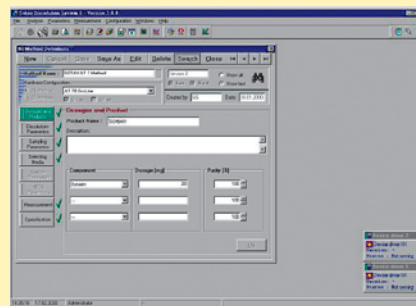
Filter station



Premium filter



Device configuration



Method screen

Hardware configuration

The system is modular in design, takes up minimum laboratory space, can be individually designed and expanded and consists of the following standard features:

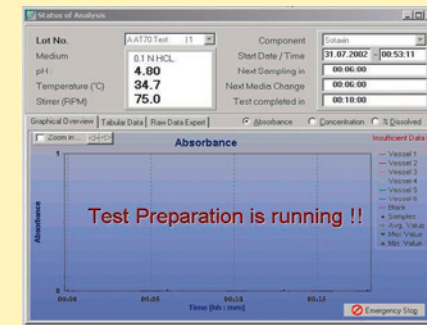
- Media selector with choice of four different test media (one is purified water).
- Deaeration system with helium.
- Tablet magazine for 7x10 or up to 7x15 samples.
- Filter station for conventional disposable filters consisting of various materials and multiple pore sizes. The filter station is adjusted to accommodate PALL standard syringe filters and the specially designed Premium filters. Filters of other manufacturers have to be tested for compatibility.
- On-line system with direct photometric evaluation utilizing different spectrophotometers.
- Off-line system with sample collection into a fraction collector for subsequent processing and analysis (e.g. dilution, HPLC etc.).
- Combined on-line/off-line system for both direct evaluation and/or sample collection.

Optional features

- Media preparation using concentrates (1:10–1:40) for up to 8 different media.
- pH monitoring.
- Standard monitoring for up to 6 standards.
- Tablet magazine for up to 15 samples (apparatus 2 testing).
- Basket testing with SOTAX Basket Station BS 60.
- Virtual dilution through cell grouping utilizing a 16-fold cell changer with two different path lengths, dilutions up to 1:20 are possible.
- Pellet testing with pellet device for up to 15 samples in series.

WinSOTAX Advanced Dissolution Software

- Fully 21 CFR Part 11 compliant.
- Easy to operate user interface with simple menus and dialogue boxes.
- Controls rpm, temperature, off-line functionality, on-line modules for UV/VIS spectrophotometer measurements with the most common spectrophotometers.
- Calculation of concentration and percentage dissolved including statistical functions and multicomponent analysis.
- Batch processing allows the performance with a SOTAX AT 70smart of up to 15 different tablet tests.
- Interface for pH measurements of media.
- Standard monitoring procedures.
- Virtual dilution with 16-fold changer.
- Raw data maintained for verification at any time and audit trail for all operations. Protocol of recorded rpm, temperature, pH including statistical functions min/max, mean and standard deviation.
- Excipient (placebo) or impurity subtraction during data calculations.
- Menu-driven report generator allows for user to create tailor-made reports.
- Fast 32 Bit design for Windows 2000/XP, on-line help system for context-based system information.
- USP S1, S2, S3 test protocol and result comparison procedures.



Test preparation

Operation

The SOTAX AT 70smart Dissolution System is controlled by a PC using the WinSOTAX dissolution software. In the WinSOTAX software all test methods used in a lab are kept in a database. A test method containing the appropriate parameters for test preparation, test execution and system cleaning can be created and then utilized. Up to 15 methods with different parameters (such as test medium, temperature and speed, test duration, sample processing etc.) can be loaded and run for each batch.

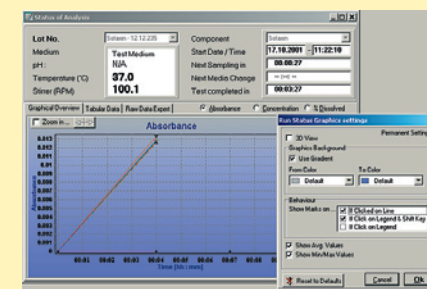
The operating functions are divided into three areas:

Test preparation

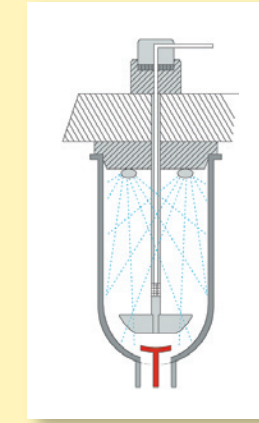
- Choice of test medium: The medium selector permits a choice between three prepared dissolution media, plus deionized water at a fourth position.
- Medium preparation: The selected medium is heated to the programmed temperature in the preparation tank (10 liters). After reaching the set temperature the medium is quickly and efficiently degassed using helium. The consumption of helium is minimal due to the efficient design. After the media is preheated and degassed, the SOTAX dosage pump quickly and accurately delivers the medium from the preparation tank into each of the 7 vessels simultaneously. Filling is a gentle process, through the valves at the bottom of the test vessels, preventing any renewed uptake of oxygen by the medium. Dosage speed is 300 ml/min per vessel, so that all the test vessels are filled with preheated and degassed test medium within 1½ – 3 minutes. Since the media delivery is without any turbulence the use of media containing modifiers as SDS/SLS is possible.
- Tablet feeder device holds up to 6 or 7 specimens per test. There are tablet holders with different diameters available for a maximum of 15 tests. The specimens are simultaneously dropped into the test vessels in a program-controlled procedure.
- Filtration: Before each test or after each sampling or medium change, the filter unit is automatically fitted with 7 new filters from the carousel magazine according to the operating method.
- Test series: Up to 15 dissolution tests - on 6 or 7 specimens each - run automatically according to individually preselected methods.

Test execution

- Tablet feed: Specimens are dropped simultaneously into the test vessels from the tablet feed device; for baskets the Basket Station BS 60 controls the sample introduction.
- Sampling: Specimens are drawn simultaneously on 7 channels and filtered. To rule out any contamination due to the previous withdrawal (carryover effect), the entire circulation tubing throughout the sampling system is purged before sampling or measurement.
- On-line measurement: An integrated photometer with cell changer (at least 7 flow-through cells) is utilized for direct photometric evaluation. This prevents any loss of volume in the test vessels as a result of sample withdrawal. The system software also controls all operating functions of the photometer and controls the data collection and evaluation.
- Off-line sampling: Samples and the blank/placebo solution are collected in the SOTAX C 615 fraction collector and then separately evaluated at a later time. Volumes from 2 to 60ml can be collected for a maximum of 29 time points. Samples can, for example, be filled directly into HPLC vials. The cells/vials are covered with a PVC foil immediately after filling to prevent evaporation or contamination of the samples. Fresh solvent can, if required, replace the sample volume removed.
- Combined on-line/off-line operation: In this mode of operation, samples can either both be measured directly in the photometer and collected for separate evaluation.



Test run



Cleaning with rotating shower heads under 56 psi/4 bar pressure

Test end and cleaning

- Emptying: The test vessels are emptied very quickly through the drain valve at the bottom of the vessel. A sieve in a collection container retains any sample residue or capsule weights that were used during the test (sinters,...).
- Medium volume control: This feature makes it possible to validate the amount of medium effectively used in each test vessel by a gravimetric measurement and to record this accordingly in the test report. This is done by weighing the content of each test vessel on a precision balance after the test and documenting the appropriate volume.
- Cleaning the system: Thorough cleaning of all components coming into contact with the medium or any dissolved sample is important to exclude the risk of contaminating subsequent tests. The cleaning is executed under 3–4 bar water pressure with rotating cleaning heads. The system has a carryover of less than 0.1% (as content of the new solution at the start in relation to blank solvent). Test vessels, stirrers, filter station and the entire tube system are thoroughly flushed with deionized water. The cleaning cycle can be run once or multiple times in succession, depending on the users' needs. In addition, the entire system is flushed with the current test medium prior to the start of each test.
- Changing the filter: Before the system is cleaned, used disposable filters are ejected from the filter station and the filter station is flushed thoroughly (without filters) during the cleaning cycle. New disposable filters are then fed into the filter station before the next test begins. If filter change at each sampling point is selected then the filters are changed as needed during the test.

WinSOTAX advanced dissolution software controls the entire functional sequence of the system. Automatic monitoring functions ensure optimum functional efficiency. For example, a test can only start when the test vessels have reached the correct temperature or the test will not run when the filter station is empty. Overflow sensors prevent overfilling of the test vessels. Medium loss is recorded and documented during the volume control after the end of a test. System software capabilities required by many laboratories.

SOTAX BS 60 Basket Station

The SOTAX BS 60 Basket Station is attached to the SOTAX AT 70smart and provides a flexible and fully automatic dissolution system for USP 1. The system configuration ensures that no carryover is possible as the basket transport system is separate for new and tested (wet) baskets; it uses a different path.

The SOTAX BS 60 Basket Station has the following features:

- 10 dissolution tests, each with 6 baskets in unmonitored permanent operation.
- 6 carousel magazines with helium purge feature.
- Simultaneous placing and removal of the baskets.
- Simple to clean.
- Used baskets slide into a collection container filled with water after the test.
- High level of operational security with monitoring sensors.
- Automatic lifting of the stirring unit of the AT 70smart when changing baskets.
- Very robust and reliable construction.

High productivity gain with short return on investment

The fully automatic SOTAX AT 70smart Dissolution Testing System permits the efficient running of serial tests thanks to extremely short intervals between tests.



SOTAX Basket Station BS 60 carousel magazines