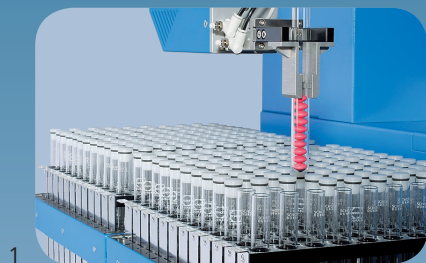


The fastest and most reliable system for automated Content Uniformity and Composite Assay testing on the market!

- ▶ **Simultaneous** sample processing
- ▶ Up to **240 samples** in 16 x 160 mm tubes or up to 80 samples in 32 x 115 mm tubes
- ▶ Sample volumes from **25 to 1000 ml** of solvent
- ▶ Superior handling of tablets, capsules, effervescent tablets, powder, pellets, and liquids
- ▶ Complete control via 21 CFR Part 11 compliant software with LIMS access

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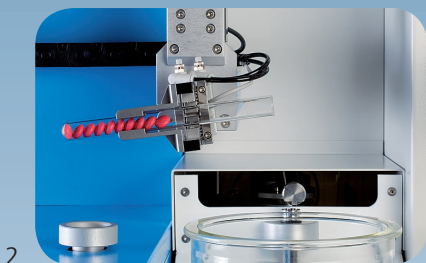




1

Sample Magazine and Sample Input

- ▶ The unique Sotax designed sample magazine can run in a basic version up to 120 (tube size 16 x 160 mm) or 40 (tube size 32 x 115 mm) samples in an unattended operation/sequence.
- ▶ With the extend version of the sample magazine it is possible to run up 240 samples (tube size 16 x 160 mm) or 80 (tube size 115 mm). This unique design allows greater flexibility for the introduction of a wide sample range (tablets, capsules, powder, pellets, liquids, Blend Uniformity and effervescent tablet).
- ▶ The number of tests to be performed is not dependent on the number of dilution steps.
- ▶ Sample weights are recorded using a 4-place Mettler-Toledo balance.



2

Solvent Input

- ▶ With an optional rinse station the test tubes can be washed out with a selectable solvent to allow a quantitative transfer from your sample.
- ▶ 8-port valve allows greater flexibility for complex methods. Solvent introduction into the vessel is via a CP1-300 ceramic pump.
- ▶ Density correction via built in temperature probe for environmental compensation.
- ▶ Solvent introduction for the last 5 % of required volume is dispensed to a precision of drop wise accuracy. Multiple solvent additions for a single analysis.



3

Homogenizer

- ▶ Programmable up to a max speed of 15K rpm.
- ▶ The design feature of locating the bearings at the top of the tool ensures that at no time during the homogenization step heat is transferred to the solvent during the extraction.
- ▶ Cleaning cycle requires a minimum amount of organic solvent for washing.
- ▶ Software allows programmable individual set up times for homogenization and wash cycle.
- ▶ Optional homogenizer with an integrated temperature sensor, for measurement of solvent temperature during the homogenization process.



4

Sample Output and Sampling

- ▶ Sample transfer is carried out using a syringe pump coupled to a standard filter station.
- ▶ The filter station gives the user the added flexibility of using industry standard filters from a range of manufacturers.
- ▶ SOTAX recommends using Pall Automation Certified Filters.



5

► **Off-line Sampling**

Allows samples to collect in capped vials (2 ml or 20 ml).

► **On-line Sampling**

Allows samples to be directly injected into one or two HPLC systems or one UV/VIS spectrophotometer.

► **Off/On-line-Sampling**

Provides real user flexibility, by performing real time on-line analysis by direct injection as well as off-line sample collection simultaneously.

During system cleaning used filters will be discarded and the sample line flushed with selectable reagent.

Test End and Cleaning

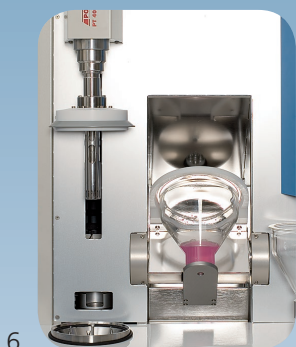
► **Emptying and Cleaning of the Vessels**

The vessel is emptied and cleaned effectively and efficiently with solvents that may be selected by the user or a default solvent. The solvents are introduced by spray nozzles located at angles in the cleaning station.

Only approx. 25 ml of an organic solvent might be required for washing, the vessel will be sprayed and dried with filtered air.

► **Cleaning of the Homogenizer**

After the extraction step it will move into a wash station and a flexible cleaning process starts with drying at the end.



6

Validation and Qualification

The SOTAX CTS Content Testing System has been developed according to ISO 9001-2000 quality standard and meets all requirements of the GAMP and GALP guidelines. The hardware as well as the CTsoft Software have been thoroughly 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 regular recurring system calibration is also provided.

CTsoft Software

Fulfills the requirements of the rules and regulations of 21 CFR Part 11 – Electronic Record; Electronic Signatures from the FDA department of Health and Human, dated on March 20, 1997.

- Fully 21 CFR Part 11 compliant
- High security through closed system with password access and different user rights assignable. Periodic password changes and user lock out after failed log-on selectable
- Complete audit trail for access, test, method, and hardware changes
- Electronic signatures
- Offline database available



7

Features

- ▶ The SOTAX automated Content Testing System is manufactured with high quality, inert materials such as PVDF, stainless steel, Teflon, glass and PEEK
- ▶ Efficient cleaning design eliminates carry-over between tests
- ▶ Outstanding accuracy and reproducibility
- ▶ Flexible design concept allowing for customized requirements
- ▶ Unique rotating solvent input station allows the transfer of powder into the solvent without residue
- ▶ Dilution ratios up to 1:10,000 can be performed
- ▶ Choice of up to 8 different solvents for maximum flexibility
- ▶ Easy validation of hardware and software
- ▶ Easy re-injection of fractioned samples into HPLC at any time
- ▶ Homogenizer tool without bearing in contact with solvent
- ▶ Extraction hood
- ▶ Evaporation-resistant caps

Optional Features

- ▶ Sample rack for up to 240 samples
- ▶ PT100 for temperature measuring in the homogenizer unit
- ▶ UV/VIS interface for on-line sample readings
- ▶ Direct injection into one or two HPLC units
- ▶ Waste management with level control
- ▶ Transfer station for blend uniformity and powder methods
- ▶ Peltier-cooled off-line sample racks
- ▶ LIMS functionality

