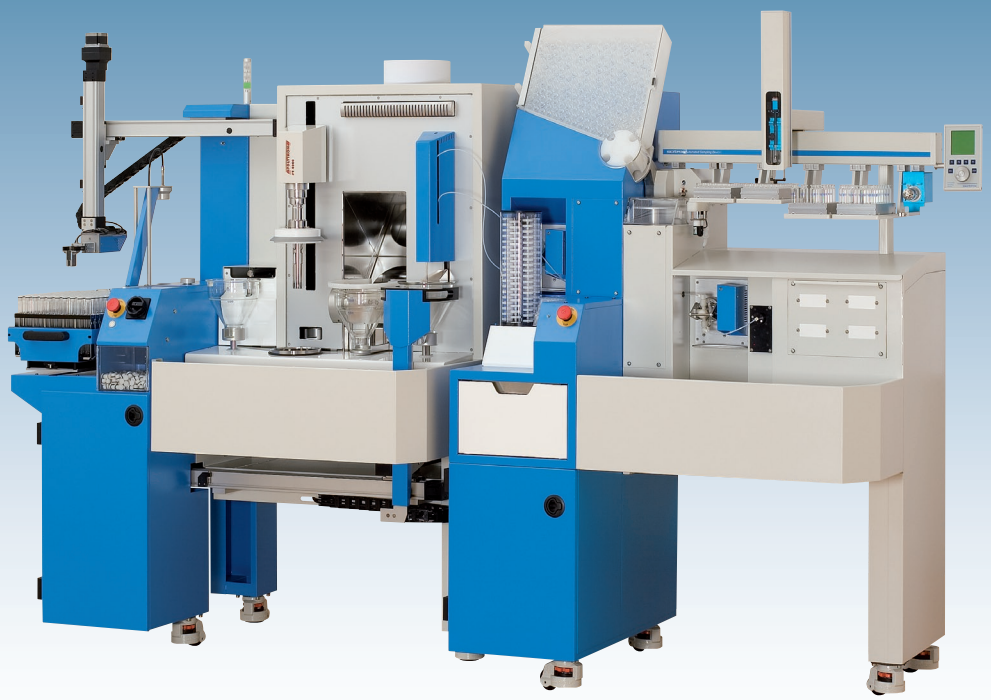
CTS Content Testing System

sotax
Solutions for Pharmaceutical Testing



SWISS QUALITY
ISO 9001

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

- **Simultaneous** sample processing, up to three times faster than comparable systems available in the market
- 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
- Brushless homogenizer motor for maintenance-free use
- Complete control via 21 CFR Part 11 compliant software with LIMS access

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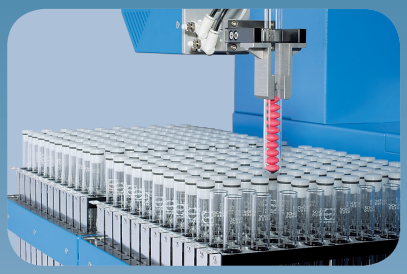
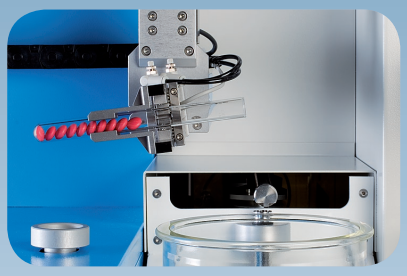


1

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.
- Over 4-digit Mettler-Toledo balance the sample weight is stored in the method protocol.



2

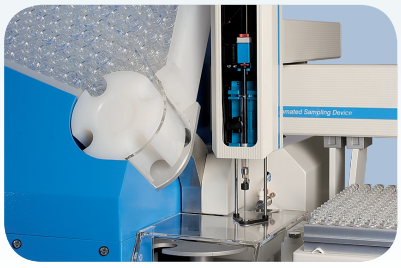
Solvent Input

- With an optional rinse station the test tubes can be washed out with a selectable solvent to allow a quantitative transfer from your sample.
- The system covers a variety of solvent variants which with an 8-channel solvent selector allows greater flexibility for complex methods. Solvent introduction into the vessel is via a CP1-300 ceramic pump.
- The CTS has a built in temperature sensor, which after measuring the ambient temperature the software will automatically calculate the density of the solvent(s) to be dispensed.
- Solvent introduction for the last 5 % of required volume is dispensed to a precision of drop wise accuracy. Several solvents may be admitted to the vessel for a single analysis.

3

Homogenizer

- The unit is fully 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 is heat transferred to the solvent during the process.
- Cleaning cycle requires a minimum amount of organic solvent for washing.
- Software allows programmable individual set up times for homogenization and wash cycle.
- Sotax can offer as an option a homogeniser with an integrated temperature sensor, for measurement of solvent temperature during the homogenization process.



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Sample Output and Sampling

- Sample output is carried out via one CP1-35 ceramic head piston 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.

1 Sample Magazine small | 2 Sample Input | 3 Homogenizer | 4 Automated Sampling Device

5

- **Off-line Sampling**
  Allows samples to collected in capped vials (2 ml or 20 ml).
- **Online Sampling**
  Allows samples to be directly injected into one or two HPLC systems or one UV/VIS spectrophotometer.
- **Off/Online-Sampling**
  Provides real user flexibility, by performing real time on-line analysis by direct injection as well as off-line sample collection simultaneously.

  Before system cleaning, used disposable filters are ejected from the filter station and the sample line is flushed with a per-defined media.

6

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 nozzles located at angles in the cleaning station.

  Only approx. 25 ml of an organic solvent is required for washing, the vessel will be sprayed and dried with filtered air.
- **Cleaning of the Homogenizers**
  On completion of the Homogenization process the unit is lowered into the cleaning station located directly under the unit.

  It is then completely cleaned and dried as per the user defined software protocols.

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

It fulfils 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.

7

- Fully 21 CFR Part 11 complaint
- 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

5 Filter Station | 6 Wash Station | 7 Multiple Sampling

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 solvents input station allows the insertion of powder into the solvent without reidue
- Dilution ratios up to 1:40,000 can be performed
- Choice of up to 8 different solvents for a 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

- Tablet magazine for up to 240 samples
- PT100 for temperature measuring in the Homogenizer unit
- UV/VIS spectrophotometer for on-line sample readings
- Direct injection into one or two HPLC units
- Complete waste management with level control
- Rinsing station for Sample Input / Blend Uniformity
- Barcode reader for common industry formats
- Peltier-cooled off-line sample racks
- LIMS functionality

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