CE7 Smart Flow-Through Dissolution USP Apparatus 4

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Solutions for Pharmaceutical Testing

SWISS QUALITY
ISO 9001

The 4th Generation of Apparatus 4 for Flow-Through Cell Dissolution by SOTAX

- **Cells** designed for MR, CR and ER tablets, capsules, suppositories, powders, pellets, APIs, implants, medical devices, ophtalmic devices, drug eluting stents, creams, gels, suspensions, microspheres, liposomes and nanosuspensions
- Suitable for **R&D and QC**, manual and automated sampling, firmware or software driven, linked to UV-Vis and fraction collector for HPLC
- **Evolution** of the original Flow-Through Cell system designed by Dr Langenbucher and SOTAX 40 years ago
- **Compliant** to USP, EP and JP for small volume dissolution and poorly soluble compound testing under sink conditions

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Technical data

6 test position	*+ 1 blank position*
Water bath capacity	*8 litres*
Temperature range	*room temperature +5°C to 45°C +/-0.2°C*
Wattage	*1100 VA*
Height	*470 mm*
Depth	*600 mm*
Width	*580 mm*
Weight	*ca. 36 kg*

Description

The SOTAX CE 7smart is the 4th generation of the Flow-Through Cell instrument designed over 40 years ago by Dr Langenbucher in collaboration with SOTAX. In this USP 4 method a test sample is placed in a specially designed cell through which media is pumped at 37°C. The eluate is filtered upon leaving the cell and can then either be analyzed by UV-Vis or collected for HPLC. The type of cell is chosen to suit the dosage form and it is permanently maintained at 37°C in a water jacket. Parameters such as flow rate, quantity of dissolution media and filtering porosity are defined during method development.

Features

The CE 7smart complies with USP chapters 711, 1088, 2040, E.P. 2.9.3, 2.9.42 and 2.9.43 and is described in the JP as JP3. The front panel keypad with graphic display shows method parameters such as sampling times, media, temperature, flow rate, cell type and volume. It uses standard cells (12 and 22.6mm), cells for powders and granulates, suppositories and soft gelatin capsules, implants, and drug-eluting stents. Inserts are available for creams, gels, ophthalmic devices, liposomes and nanosuspensions.

Ready for Automation

The CE 7smart can be linked to either a SOTAX CY 7-50 or CP 7-35 piston pumps. This mode enables samples to be taken manually. To increased productivity the CE 7smart and associated pump can be linked to a UV-Vis spectrophotometer (requiring WinSOTAXplus, the SOTAX 21 CFR Part 11-compliant dissolution software controlling all USP 1, 2, 5, 6 SOTAX dissolution instruments) or a fraction collector for HPLC (firmware-driven or WinSOTAXplus-driven). The UV-Vis spectrophotometers used can be of any major brand including the SOTAX Specord Plus solution. The WinSOTAXplus has a client/server architecture that allows a multi-system installation.

Validation and qualification

The Flow-Through Cell system must be calibrated and qualified just like any other compendial dissolution system. The OQ of the system is based on two physical parameters: the temperature and the flow rate. Temperature is measured in the bath, before the cell and in each cell. Flow rate is measured gravimetrically using either a fully automated validation station (option), the fraction collector (off-line system) or a pump calibration media collection station (on-line system). All these measurements are performed and documented in accordance with the SOTAX Qualification Plan and are provided as part of a SOTAX Services Maintenance/Qualification contract.

Accessories

- For details of cells and other accessories, please refer to: www.sotax.com

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