

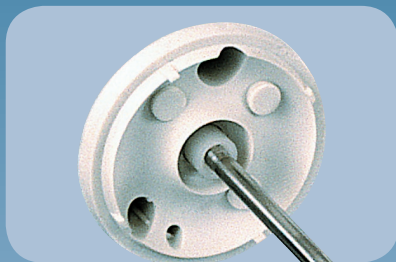


The smarter choice for dissolution testing

- ▶ **Compliant with** all pharmacopeia 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
- ▶ **Compact, space-saving** design with built-in heater/circulator and staggered vessels for easy sample viewing
- ▶ Fixed position shaft height, built-in evaporation covers for **auto vessel centering**, fully conforms to USP and ASTM Mechanical Calibration
- ▶ Program **dissolution methods** in firmware to assist in sample introduction and sampling times
- ▶ **Modular Concept** allows for future upgrades to automation with addition of autosampler, on-line spectrophotometer, UV Fiber Optics or Automated Sampling Device

www.sotax.com | e-mail info@sotax.com





Integrated vessel cover



Validation Checklist



Technical data

Test stands	7
Temperature	20 – 45°C
Range	+/-0.2°C
Speed range	25 – 250 rpm
Power supply	230 V/50 Hz or 110 V/60 Hz
Interface	RS-232-C
Width/depth	595/520 mm
Height	420 mm
Weight	ca. 35 kg

Description

The SOTAX AT 7smart dissolution testing unit determines the in-vitro drug release from common pharmaceutical dosage forms according to pharmacopoeia requirements. The AT 7smart is the result of 35 years of development, manufacturing and experience from our customers. Since it takes up a minimum amount of space, it fits into any standard test laboratory. From its exceptional userfriendliness, the SOTAX AT 7smart is particularly noted for its high manufacturing quality and robustness after years of use. The AT 7smart was developed under ISO 9001 utilising the Autocompliance™ concept. This ensures that the time devoted to validation is significantly less than for other units.

Features

The AT 7smart conforms to the latest USP, JP, EP and FDA/ASTM guidelines for apparatus specifications and calibration and the SOTAX AT 7smart can be used for dissolution tests using the USP methods 1 (Basket), 2 (Paddle), 5 (Paddle-over-disk) and 6 (Cylinder). Using the front panel key pad with graphic display test parameters like temperature, speed, tablet introduction and sampling time may be programmed. These parameters can also be printed directly from the unit. Integrated vessel covers ensure automatic vessel centering and precise positioning of the stirrers without additional tools. Due to the closed design, evaporative loss on evaporation is < 0.5 % in 24 hours at 37 °C.

Ready for Automation

The AT 7smart can be automated at any time to collect samples with a fraction collector, analyze samples with an on-line spectrophotometer or both. The modular concept permits substantially tailor-made automation solutions. Options including "Hollow Shaft" sampling shafts with filter heads, automated media replacement and media addition, automated tablet drop, automated filter changes and On-line HPLC injections.

Without additional PC and software:

- ▶ Control of automatic tablet input at programmed time.
- ▶ Control of off-line sampling with fraction collector for collection into test tubes or capped HPLC vials.

With WinSOTAX advanced dissolution software (Windows 2000/XP/Vista):

- ▶ On-line system with direct photometric evaluation.
- ▶ On-line HPLC system with injection directly into the HPLC unit.
- ▶ Off-line system with sample collection in the fraction collector.
- ▶ Combined on-/off-line system for direct evaluation and/or sample collection or system with multiple baths. Dual bath collection with fraction collector or analysis with spectrophotometer.

Validation and calibration

The SOTAX AT 7smart dissolution bath meets all requirements for validation, qualification and regular calibration intervals according to the USP and FDA procedures. With the unique Autocompliance™ design concept your validation time is reduced. Frequent checks of the stirrer height, centering, shaft wobble or sampling position are not necessary. The optional SOTAX validation check set can be purchased to measure these requirements. SOTAX also offers the ASTM Mechanical Calibration checkset. All SOTAX systems include IQ, OQ and PQ documentation to fulfill GMP/GLP requirements. The AT 7smart is also supported by SOTAX Services for in-lab installations, qualifications, service contracts and user trainings.