



An intelligent way of Disintegration Testing

- ▶ Disintegration time testing unit with **two basket-rack** assemblies
- ▶ **Each basket-rack** assembly can be controlled, started and stopped **individually** reporting of disintegration time
- ▶ **Automatically** lowers the baskets at test start and raises the baskets at test end
- ▶ **Optional automated detection of disintegration** end point based on contact of the USP fluted disk with stainless steel mesh for individual test results
- ▶ Operating conditions programmable on front key pad with graphic display
- ▶ Report printout with test results, statistics and temperature protocol
- ▶ Conforms to the latest USP <701> and <2040> chapters for disintegration testing

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





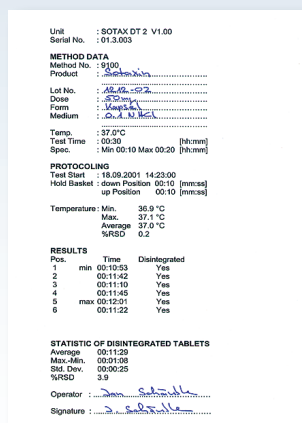
Automation basket (also available with 3 tubes for big capsules and tablets)

Specification

No. of baskets	2
Strokes per minute	30 +/-1
Height of stroke	55 mm
Temperature	20 – 45°C +/-0.2°C
Power	230 V/50 Hz or 110 V/60 Hz
Interfaces	RS-232-C Parallel
Width/depth/height	370/410/550 mm
Weight ca.	23 kg

Order information

Part #	Description
9000-1 or 2	SOTAX DT 2
8610	Automated lift-in/out
3061-1	Glass beaker
2044-1	Baskets
2134	Glass tube
3063	Disks
Automation option:	Ask for a quote



Report

Description

The user-friendly SOTAX DT 2 unit is equipped with two basket-rack assemblies. Each basket-rack assembly can be controlled, started and stopped individually. An integrated powerful water circulation system guarantees a precise temperature of the test medium. The temperature can be set between 20–45°C. The movable PT 100 temperature probe accurately monitors the temperature in the beaker or in the bath during the test run. The actual temperature is shown on the display. Special emphasis has been placed on an accurate and play-free travel hoist mechanism.

Features

The program allows the user to take individual disintegration time of both basket-rack assemblies. A report printout of the test method, with results, statistics and temperature protocol is possible. Up to ten individual methods can be stored and used any time. Baskets feature an automated lift-in and lift-out at beginning/end of the run-time or when a pH change occurs. An acoustic signal after completion of each pre-set run-time is selectable. The setting and the calibration of the temperature are controlled by the program menu. The SOTAX DT 2 is manufactured from high quality materials. The housing is made of galvanized, powder-coated sheet steel. The DT 2 has minimal regular maintenance.

Automation

The disintegration time is a routine test which requires a user to monitor the test until tablets are completely disintegrated. The test cannot always be done by visual observation as some dosage forms give very turbid solutions which limits visibility or debris such as undissolved coating material or gelatin remain in the tube. This leads to variable, non accurate and out of range test results. The SOTAX automation option works with electrically conductive disks. Test end is reached when the disks give contact with the USP stainless steel mesh. This is a very reliable way to determine the end point. The option includes a disintegration time control unit with modified USP disks. Automated disintegration time tests help to overcome routine work and give more accurate results.

Optional features and accessories

- ▶ Special USP disk for capsules allows testing of gelatin capsules.
- ▶ Basket with only 3 tubes to test big capsules and tablets according to the pharmacopoeia requirements.
- ▶ Q-Doc integrated disintegration software with a PC. Q-Doc permits storage of a large number of methods as well as test reports. Q-Doc is a validated Windows 2000/XP software which fully complies with 21 CFR Part 11.

Validation and qualification

The SOTAX Disintegration Tester DT 2 meets all pharmacopoeia requirements. The appropriate qualification documentation (IQ/OQ) can be supplied with each system. Q-Doc disintegration software is delivered with IQ documents and a validation certificate. If required, system validation and qualification can also be carried out in the customer's laboratory by SOTAX staff or SOTAX agents.