



## The most efficient way of disintegration testing

- ▶ Disintegration time testing unit with two basket-rack assemblies
- ▶ Each basket-rack assembly can be controlled, started and stopped individually for individual disintegration time tests
- ▶ Automatically lowers the baskets at test start and raises the baskets at test end
- ▶ Acoustic signal on completion of test run time
- ▶ Electronic temperature sensor for display and documentation of temperature in each beaker
- ▶ Operating conditions programmable on front key pad with graphic display
- ▶ Report printout with test results, statistics and temperature protocol
- ▶ Connection to PC with RS-232-C and to printer with parallel interface
- ▶ Automated detection of disintegration end point based on contact of the USP fluted disk with USP stainless steel mesh
- ▶ Validated Windows 2000/XP Q-Doc disintegration software which fully complies with 21 CFR Part 11

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

### Technical data

No. of baskets	2
Strokes per minute	30 +/-1
Height of stroke	55 mm
Temperature	20 – 60°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	Glass beaker
2044-1	Baskets
2134	Glass tube
3063	Disks
Automation option:	Ask for a quote

Unit : SOTAX DT 2 V1.00  
Serial No. : 013.003

METHOD DATA  
Method No. : 9100  
Product : *Sildenafil*

Lot No. : *12.02.02*  
Dose : *50mg*  
Form : *Capsule*  
Medium : *0.1 N HCl*

Temp. : 37.0°C  
Test Time : 00:30 [h:mm:ss]  
Spec. : Min 00:10 Max 00:20 [h:mm:ss]

PROTOCOLING  
Test Start : 18.09.2001 14:23:00  
Hold Basket : down Position 00:10 [mm:ss]  
up Position 00:10 [mm:ss]

Temperature : Min. 36.9 °C  
Max. 37.1 °C  
Average 37.0 °C  
%RSD 0.2

Pos.	Time	Disintegrated
1	00:10:23	Yes
2	00:11:42	Yes
3	00:11:10	Yes
4	00:11:45	Yes
5	00:12:01	Yes
6	00:11:22	Yes

STATISTIC OF DISINTEGRATED TABLETS  
Average : 00:11:29  
Max./Min. : 00:12:01 / 00:10:23  
Std. Dev. : 00:00:25  
%RSD : 2.9  
Operator : *Jan Schürle*  
Signature : *Jan Schürle*

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 20–60°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. The basket cannot roll or swing.

### 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 set 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 no regular maintenance.

### Automation

The disintegration time is a routine test which requires a staff member to monitor it until tablets are completely dissolved. The test cannot always be done manually as some dosage forms give very turbid solutions with no or limited visibility or debris such as coating material or gelatin remain in the tube. This leads to variable 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. The following options are available for the DT 2 automated unit:

- ▶ Special USP disk for capsules allows testing of gelatin capsules.
- ▶ Q-Doc integrated disintegration software with a PC. Q-Doc permits storage of a large number of methods as well as test reports. Customized reports are also possible. Q-Doc is a validated Windows 2000/XP software which fully complies with 21 CFR Part 11. Q-Doc is also available with LIMS capabilities.

### Optional features and accessories

- ▶ Basket with only 3 tubes to test big capsules and tablets according to the pharmacopoeia requirements.

### 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.