HT100 Tablet Testing System

sotax
Solutions for Pharmaceutical Testing

SWISS QUALITY
ISO 9001

The fastest automated tablet testing system with the revolutionary Auto Alignment™ and Auto Separator device ensures consistent, trouble-free results for all shapes and sizes of tablets batch after batch.

- Automated testing of the most important physical parameters (weight, thickness, diameter or length and hardness) of up to 10 different products or batches, e.g. tablets, dragées, oblongs, effervescent tablets or similar drug delivery systems
- Separates all shapes and sizes of tablets with ease, using the vibration-free Auto Separator, no manual adjustments required
- Equipped with the Auto Alignment™ device (patented) which automatically aligns even the most difficult of tablet shapes, to prevent erroneous hardness measurements
- Two hardness measurement principles “Constant Speed” and “Constant Force”, measuring range as standard 4 to 500 or 1000 N
- Controlled by our 21 CFR Part 11 compliant and LIMS capable Q-Doc software for Windows 2000/XP/Vista
- Meets the USP chapter 1217 requirements: three points calibration and tablet orientation

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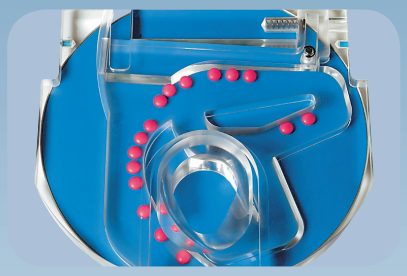
1

Ten-chamber feeder

- The optional batch feeder has ten chambers. Each chamber can hold 200 samples or more (dependent upon size and shape). Chambers may be filled with different batches of tablets or combined as one large single batch.
- The feeder cover serves two purposes, namely to load samples into the chamber and to protect the tablets against dust. The magazine is easily removable and easy to clean.
- The feeder moves clockwise and transports the samples into the Auto Separator.



2

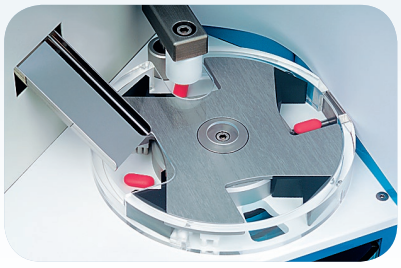
Auto Separator

- With the Auto Separator it is possible to separate all shapes and sizes of tablets without any manual user adjustments or special tools.
- The separation is achieved through a new device based on soft rotation (instead of vibration).
- The Auto Separator is removable and can be easily cleaned.
- A photoelectric sensor is positioned on the outside of the separator to detect each individual sample as it is deposited from the separator to the balance boat.

3

Balance boat

- The weight of each sample is determined using a balance boat and this is designed to eliminate errors caused by a build-up of tablet debris and dust.
- The tablet weight is measured with a high-speed, precise Mettler weight cell.
- The weight cell is positioned separately from the SOTAX HT 100 housing. The two balancer screws on the Mettler weight cell are easily accessible for leveling the balance boat.
- The balance boat is equipped with two slides, enabling to check only the weight of gelatin capsules or other samples before being collected in a special container.
- The balance boat can be removed easily for cleaning.
- The tablet is moved smoothly from the balance boat into the transporter.

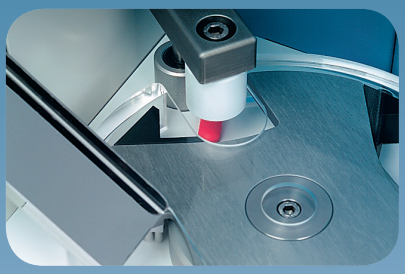


4

Transporter

- The four-station transporter feeds the tablet clockwise from each test station.
- The Auto Alignment™ device (patented) on the hardness testing station guarantees that all common forms are positioned correctly.
- The feed path and the test jaw are automatically cleaned of tablet debris by special brushes mounted on the transport head. Broken tablets are automatically swept away into a waste container.

1 Ten-chamber feeder | 2 Auto Separator | 3 Balance boat | 4 Transporter



5

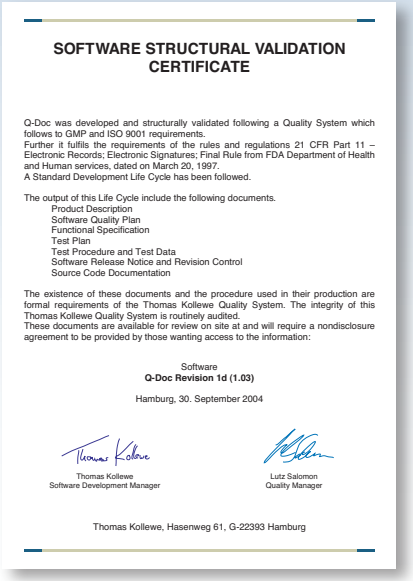
Thickness measuring system

- Thickness is measured by calibrated precision potentiometric displacement sensors.
- The measuring plate is ball bearing supported for easy adjustment and to ensure that this plate remains parallel to the test platform.
- The thickness measuring system is automatically zeroed after each test run.

6

Hardness measuring station

- Equipped with the Auto Alignment™ device (patented), to position automatically and rapidly all common forms at exactly 90 degrees to the test jaw before testing.
- An automated cleaning device that protects the hardness station from tablet residues is included.
- The measuring plate is ball bearing supported for an easy adjustment and to ensure that it remains parallel to the test platform.
- Measurement by “Constant Speed” or by “Constant Force” is selectable. The jaw speed movement and the linear increase of force are adjustable.
- These techniques compare and reproduce results of all common hardness testers.



SOFTWARE STRUCTURAL VALIDATION CERTIFICATE

Q-Doc was developed and structurally validated following a Quality System which follows to GMP and ISO 9001 requirements.
Further it fulfils the requirements of the rules and regulations 21 CFR Part 11 – Electronic Records; Electronic Signatures; Final Rule from FDA Department of Health and Human services, dated on March 20, 1997.
A Standard Development Life Cycle has been followed.

The output of this Life Cycle include the following documents.

Product Description
Software Quality Plan
Functional Specification
Test Plan
Test Procedure and Test Data
Software Release Notice and Revision Control
Source Code Documentation

The existence of these documents and the procedure used in their production are formal requirements of the Thomas Kollewe Quality System. The integrity of this Thomas Kollewe Quality System is routinely audited.
These documents are available for review on site at and will require a nondisclosure agreement to be provided by those wanting access to the information:

Software
Q-Doc Revision 1d (1.03)

Hamburg, 30. September 2004

Thomas Kollewe
Software Development Manager

Lutz Salomon
Quality Manager

Thomas Kollewe, Hasenweg 61, G-22393 Hamburg

Q-Doc hardness tester software

- Q-Doc is a powerful software package for Windows 2000/XP/Vista, permitting the storage of methods and test results for weight, thickness, diameter or length and hardness.
- A modern and user-friendly interface allows ease of operation and a high level of data security. The Q-Doc software is fully 21 CFR Part 11 compliant.
- The easy mode system allows users fast and simple software handling. High level security is guaranteed by a closed system with password and different assignable user rights.
- Periodic password change and user log-out after failed log-on is selectable. Complete audit trail of access, test, method and hardware change.
- Q-Doc is also available with LIMS capabilities and can be networked.

Test report

- The reported test results can be printed out, stored in the database, validated and/or sent to a network secure location.
- **Hardware configuration**
  Pentium IV
  256 MB RAM
  CD-ROM drive
  Min. 800 x 600 resolution, 1024 x 768 recommended

5 Thickness measuring system | 6 Hardness measuring station

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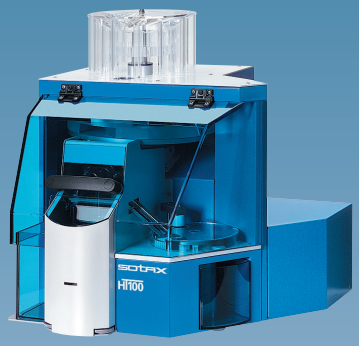

Technical data

Measurement Principles	*Constant Speed, Constant Force*
Range	*5 – 200 mm/min. (0.20 – 3.94 in) 10 – 100 N/sec*
Measuring Range	
Hardness Accuracy	*4 – 500 Newton +/-1 Newton*
Diameter	*0.00 – 30.00 mm (0.00 – 1.18 in)*
Accuracy	*+/-0.02 mm*
Thickness	*0.00 – 18.00 mm (0.00 – 0.71 in)*
Accuracy	*+/-0.02 mm*
Weight Accuracy Power	*0 mg – 60 g +/-0.1 mg 230 V/50 Hz or 110 V/60 Hz*
Interface	*RS-232-C*
Width/depth/height	*503/483/560 mm (19.80/19.02/22.05 in)*
Weight ca.	*39 kg (85.98 lb)*

Order information

Part #	*Description*
8600-01	*SOTAX HT 100 500 N*
8600-02	*SOTAX HT 100 1000 N*
8770	*Ten-chamber batch feeder*
9120	*Cover with funnel for product feed (without feeder chambers)*
9276	*Set for manual weight calibration (weight stone not included)*
	Weight:
W005-0090	*5 kg (11.03 lb)*
W005-0100	*10 kg (22.06 lb)*
W005-0110	*20 kg (44.13 lb)*
	Gauge:
W005-0200	*b. 5 mm (0.20 in)*
W005-0270	*b. 10 mm (0.39 in)*
W005-0220	*b. 20 mm (0.79 in)*

Description

- The SOTAX HT 100 automatically measures tablet weight, thickness, diameter or length and hardness for up to 10 different products or batches (e.g. tablets, dragées, oblongs, effervescent tablets or similar drug delivery systems).
- By using the Auto Separator device, all shapes and sizes of samples can be separated automatically without the need of manual user adjustments and special tools.
- The unique Auto Alignment™ device (patented) aligns samples correctly, preventing erroneous hardness measurements.
- The measurement principles are easily switched between "Constant Speed" and "Constant Force".
- The SOTAX HT 100 is an economical and indispensable tool for the in-process measurements required in production or in quality control and research & development laboratories of pharmaceutical companies.

Features

- The SOTAX HT 100 is equipped with the unique Auto Alignment™ device (patented) that automatically and instantaneously aligns the sample in the correct measurement position for hardness testing.
- The measurement principle of tablet hardness can be changed from "Constant Speed" (where the test jaw is moved at a constant speed adjustable from 5–200 mm/min.) or to "Constant Force" (where the test jaw increases force linearly adjustable from 10–100 N/sec). This feature is easily selected before each test and can be used to compare and reproduce results for all common hardness testers available on the market as well as an excellent research tool.
- The SOTAX HT 100 is manufactured of top-quality materials. The housing is made of galvanized, powder-coated sheet steel. No regular maintenance is needed.

Optional accessories

- Ten-chamber feeder
- Gauge blocks incl. certificate
- Weights
- Built-in computer

Validation and qualification

- The SOTAX family of Hardness Testers meets and exceeds all pharmacopoeial requirements.
- The appropriate qualification documents (IQ/OQ) can be supplied with each system. Q-Doc software is delivered with IQ documents and all validation certificates. When required, system and software installation, validation and training can be carried out by a certified SOTAX service engineer or one of its agents located worldwide.

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