



MQD

For simple and accurate mechanical calibration.



sotax
Solutions for Pharmaceutical Testing

Regulatory Specifications and Recommendations

Changes since 2007 in regulatory specifications now also allow enhanced mechanical calibration of dissolution systems as a valid alternative to USP PVTests.

- FDA guidance for industry (CGMP)
- Implementation Guidance for ASTM (E2503-07)
- ICH Harmonized Tripartite Guideline (Q4b Annex 7 (R2))
- Dissolution Toolkit (USP)

More and more people in the pharmaceutical industry are therefore adopting the new regulatory guidelines for enhanced mechanical calibration of dissolution systems.

SOTAX Solution for Enhanced Mechanical Qualification: MQD

The SOTAX MQD helps to improve and simplify the implementation of the enhanced mechanical calibration for any dissolution bath (USP 1 and 2) regardless of brand. It simplifies the overall qualification workflow and eliminates the complex qualification tool kits.



- Benchtop level
- Basket depth
- Paddle depth
- Rotational speed
- Shaft wobble
- Shaft verticality
- Basket wobble
- Vessel / shaft centering
- Vessel verticality
- Vessel plate level
- Bath Temperature
- Vessel Temperature



Design

- **Universal tool:** Works with any dissolution system (USP 1 and 2), supplier-independent, for open and closed head designs, manual / semi- / fully automated systems; also works with 1 L and 2 L vessels (independent from vessel height)
- **Latest available measuring technologies:** allow wireless in-situ measurements
- **Compact and robust design:** no moving parts



Regulatory Compliance

- **100% regulatory compliance:** all measuring points as per regulatory requirements according to USP chapter <711> and FDA guidance for industry (§ 211.160 (b)(4)); regulatory specifications are stored in firmware, changes via firmware / software update
- **Selectable qualification norms:** choose between USP, FDA, ASTM
- **Raw data storage on firmware:** raw data is not kept in the software, hence, no 21 CFR Part 11 compliance required
- **Automatic compliance check:** all parameters measured are reported in physical units [mm/ % / °C] and compared to specifications (automatic compliance check, no interpretation of tool readouts or calculations performed by the analyst)

Data Acquisition and Measuring

- **In-situ measurements:** most parameters are measured in-situ
- **Wireless data transfer:** data transferred via Bluetooth to computer for reporting
- **Contactless measurements:** no risk of damaging coating or glassware (vessels)
- **Electronic data acquisition and reporting:** eliminates manual reading and reporting errors and provides reliably precise data

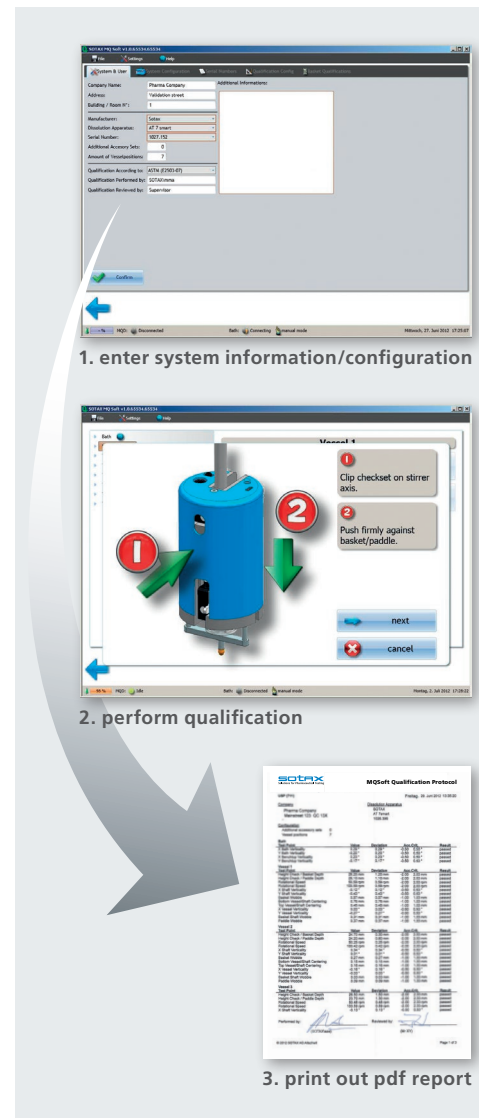


Software / Firmware

- **Plug & Play software:** communicates via Bluetooth with MQD
- **Intuitive software:** guides the user through a simple step-by-step protocol to complete the qualification
- **Serial number retention:** system data such as instrument type, serial numbers, and additional sets of accessories are stored in order to simplify routine qualifications

User

- **Simple handling:** tool can easily be clipped onto shaft, and the qualification executed in only a few manual steps
- **Reliably precise data:** no user interaction is required during measurements which eliminates manual handling and reading errors
- **Reduced qualification effort at zero risk:** automatic data acquisition and reporting allows efficient execution of qualification



Documentation

- **Automatic reporting:** Increased reliability due to automated data integration (no manual readings / reporting)
- **Reduced paperwork:** SOP guide via software, automated PDF report created upon completion

Calibration

- **Complete calibration and certification:** NIST traceable calibration and certification performed annually (calibration services can be covered by service contract)

SOTAX Qualification Services



Compliance Services

SOTAX multi-vendor services can simplify your instrument qualifications by providing a single service source for all of your dissolution baths:

- cGMP compliant qualification
- Operational and performance qualification
- Mechanical qualification
- USP Performance Verification Test (PVT)
- Customer-specific qualification

Service contracts

SOTAX service contracts provide worry-free service and compliance coverage with cost assurance. No surprises, no additional expense so you can concentrate on supporting your internal customers, not on qualification deadlines and associated paperwork:

- Regular maintenance extends equipment life
- Protect your capital equipment investment
- Long-term planning of routine service to minimize instrument downtime.
- Receive priority service response
- Cost assurance for the complete contract period (up to 5 years)

Your contacts

Europe

Switzerland (HQ Europe)

SOTAX AG

Binnerstrasse 106
4123 Allschwil 1

Tech Support +41 61 487 5460
P +41 61 487 5454
F +41 61 482 1331
services@sotax.com

France

SOTAX Sàrl.

24 avenue de Bâle
68300 Saint-Louis

Tech Support +41 61 487 5460
P +33 3 8970 0846
F +33 3 8970 1781
services@sotax.com

Germany

SOTAX GmbH

Wallbrunnstrasse 24
79539 Lörrach

Tech Support +41 61 487 5460
P +49 7621 16 5635
F +49 7621 16 5715
services@sotax.com

Great Britain

SOTAX Ltd.

13 Station Road
London N3 2SB

Tech Support +41 61 487 5460
P +44 20 8349 6946
F +44 20 8349 6948
services@sotax.com

Italy

SOTAX S.r.l.

Via Milazzo 14
24124 Bergamo

Tech Support +41 61 487 5460
P +39 035 21 9555
F +39 035 21 3643
services@sotax.com

Americas

USA (HQ Americas)

SOTAX Corp.

2400 Computer Dr
Westborough, MA 01581

Tech Support +1 508 544 4040
P +1 508 417 1112
F +1 508 616 6984
techsupport_america@sotax.com

Canada

SOTAX (Canada) Ltd.

1-335 Deerhurst Drive
Brampton, ON L6T 5K3

Tech Support +1 800 931 4151
P +1 905 494 0114
F +1 905 494 0723
techsupport_america@sotax.com

Asia-Pacific

China (HQ Asia-Pacific)

SOTAX (Shanghai) Trading Company Ltd.

800 Nanjing Road East
Room G, 15/F, No. 1 Plaza
200001 Shanghai

P +86 21 6352 1008
F +86 21 6352 2213
sotaxchina@sotax.com

India

SOTAX India (Pvt.) Ltd.

601, ECO House
Vishweshwar Nagar
Goregaon East
Mumbai 400063

P 022-429501-91 / -92
F 022-40141332
sotaxindia@sotax.com



If your country is not listed here, please view the SOTAX offices worldwide on our website www.sotax.com to find your respective service contact.

sotax
Solutions for Pharmaceutical Testing