



# 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

1. enter system information/configuration

2. perform qualification

3. print out pdf report

## 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

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