

Mechanical Qualification (MQ) Services



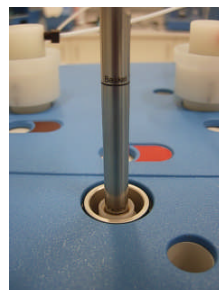
SOTAX offers Mechanical Qualification (MQ) Services and new MQ Validation Checkset



SOTAX, leader in Dissolution Testing Systems and Dissolution Maintenance and Qualification Services has now added the new Mechanical Qualification Procedure as described in ASTM E 2503-7 to our offerings.

In October 2007, the FDA issued draft guidance supporting the mechanical validation of dissolution apparatus using the Center for Drug Evaluation and Research (CDER) procedure document on mechanical qualification. At the request of our customers throughout the world, SOTAX can now assist customers who may choose to implement a Mechanical Qualification (MQ) of dissolution Apparatus 1 and 2.

The MQ procedure involves the physical measurement and reporting of critical parameters such as paddle and basket wobble, shaft verticality, shaft depth, rotational speed, vessel centering and verticality, bath levelness and vessel temperature. All SOTAX calibration tools are digital and are certified to NIST traceability. The new SOTAX MQ Validation Checkset is also available for those labs that perform their own qualifications.



SOTAX will continue to offer Performance Qualification (PQ) Services utilizing the USP Performance Verification Test method with prednisone and salicylic acid tablets. A useful strategy to implement the new MQ in your lab would involve the MQ (quarterly or biannually) with the PQ (biannually or annually).

For more details on how SOTAX can assist you in implementing the MQ and our new MQ Validation Checkset, please contact us at services@sotax.com.

