SARTORIUS

Service Datasheet

USP <1251> Certificate

Electronical Weighing Instrument

Benefits

- Reassurance during FDA audits
- Performing the metrological tests described in USP <1251> (sensitivity, linearity, eccentricity error and repeatability)
- Verification of the compliance with the tolerance specifications (acceptance criteria)
- Professional, easy-to-read certificates

Product Information

United States Pharmacopeia (USP) Chapter <1251> is entitled "Weighing on an Analytical Balance" and contains detailed information on the qualification and operation of electronic balances. The introduction specifically states that the recommendations are applicable to all balances used in the analytical process environment.

Chapter <1251> describes specific metrological tests for the "Performance Qualification" of balances and gives tolerance specifications which must be met by the balances.

Specification

- Balance test according to the USP <1251> requirements
- Performance of the following tests: sensitivity, linearity, eccentricity error and repeatability
- Documentation of the last calibration
- Repeatability is assessed by weighing one test weight 10 times
- Check whether the tolerance specification for the smallest desired customer net weight are met
- Determination of the minimum sample weight
- Testing of sensitivity, eccentricity error and repeatability with suitable test weights
- Check the results against the tolerance specifications of USP <1251>
- Creation of an easy-to-read USP <1251> certificate

Customer Prerequisites

- Device is at the maintenance site and has been sufficiently acclimatized
- The device is freely accessible

Optional Services

- Calibration certificate with ISO | IEC 17025 accreditation
- Balance test report
- USP <41> test report
- Minimum weight certificate according to the European Pharmacopoeia

Are you interested?

Get in touch with us right away. We will be happy to provide you with a non-binding service offer. You can also find further information on our website: www.sartorius.com/en/services

Germany
Sartorius Lab Instruments GmbH & Co. KG
Otto-Brenner-Straße 20
37079 Göttingen
Phone +49 551 308 0

USA
Sartorius Corporation
565 Johnson Avenue
Bohemia, NY 11716
Phone +1 631 254 4249
Toll-free +1 800 635 2906

For further contacts, visit
www.sartorius.com