SARTORIUS

Service Datasheet

USP <41> Certificate

Laboratory Balances

Benefits

- Compliance with USP Chapter <41>
- All required performance checks on accuracy and repeatability are carried out
- Certificates with as-found and as-left measurement data offered
- Ensuring peace of mind during an FDA audit

Product Information

The specifications in chapter <41> of the United States Pharmacopeia (USP) are binding for the FDA audited pharmaceutical industry. Chapter <41> is entitled "Balances" and describes specific requirements for laboratory balances that are used for substances that must be "accurately weighed". The aim is to ensure that the error resulting from the weighing application for "accurately weighed" substances is reduced to an acceptable or negligible level. In our USP <41> test certificate, the results of the performance checks are documented, and it is stated whether the customer-defined smallest net weight can be measured according to USP acceptance criteria. Additionally, a safety factor is provided, which can be used as an indicator to identify critical performance changes over the balance's life cycle.

Specification

- The certificate refers to Chapter <41> of the United States Pharmacopeia
- The required performance checks on repeatability and accuracy are carried out, their results are documented with the corresponding pass/fail statements
- Specific requirements for multi-range and multi-interval balances are taken into account
- Certificates containing as-found and as-left measurement data are issued upon request
- The last calibration is documented to establish metrological traceability of measurement results to the International System of Units (SI) is documented
- Repeatability is tested by weighing a suitable test load 10 times under constant conditions
- Determination of the minimum weight (m_{min})
- It is verified whether the user-defined smallest net weight (m_{SNW}) meets USP requirements and can be weighed on the balance
- A safety factor defining the ratio between the the smallest net weight (m_{SNW}) and the minimum weight (m_{min}) is calculated
- Accuracy is tested with a sensitivity test using a calibrated test weight and against an acceptance criterion of 0.05%

Customer Prerequisites

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

Optional Services

- Calibration certificate according to the calibration guideline EURAMET cg-18 with ISO | IEC 17025 accreditation
- Balance test report
- Minimum weight certificate according Eur. Pharmacopoeia (2.1.7.)
- USP <1251> test report

Are You Interested?

We would be pleased to hear from you! We are happy to provide you with a non-binding service quote. For more information about our service portfolio, please visit: www.sartorius.com/en/services/instrument-service

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