

USP <1251> Certificate

Laboratory Balances



Benefits

- Compliance with USP Chapter <1251>
- All required performance checks on sensitivity, repeatability, eccentric loading, and linearity are carried out
- Verification of compliance with tolerance specifications (acceptance criteria)
- Ensuring safety during an FDA audit

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. It is applicable not only to balances used for materials that must be accurately weighed, but in general to all balances used for all analytical procedures.

In our USP <1251> 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. Optionally, a safety factor can be selected as an additional acceptance criterion.

Specification

- The certificate refers to Chapter <1251> of the United States Pharmacopeia
- The required performance checks on repeatability, sensitivity, eccentric loading, and linearity, as outlined in USP Chapter <1251>, 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}) can be chosen as an additional acceptance criteria
- Sensitivity is tested with 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
- USP <41> test report
- Minimum weight certificate according to the European Pharmacopoeia

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

Learn More:




Germany

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

USA

Sartorius Corporation
3874 Research Park Drive
Ann Arbor, MI 48108
Phone +1 734 769 1600

 For further contacts, visit
www.sartorius.com