SARTURIUS

Service Datasheet

USP <41> Certificate

Electronical Weighing Instrument



Benefits

- Reassurance during FDA audits
- Achieving and maintaining compliance with USP <41>
- All binding USP tests are carried out
- Professional, easy-to-read certificates

Product Information

The specifications in chapter <41> of the United States Pharmacopeia (USP) are binding for the FDA audited pharmaceutical industry. Chapter <41> describes specific requirements for 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, thereby ensuring that the influence on the overall error remains controllable. In our USP <41> test certificate, the operating range of the balance is specified in an easily readable manner and a statement is given about the desired smallest net weight. So you are always on the safe side with all small sample weights.

Specification

- Balance test according to the USP <41> requirements
- Documentation of the last calibration
- Repeatability is assessed by weighing one test weight 10 times
- Accuracy testing with a suitable test weight
- Specification of the operating range of the balance according to USP <41>
- Check wether the smallest desired net weight is within the operating range and meets the USP <41> requirements
- Determination of the minimum sample weight
- Creation of an easy-to-read USP <41> 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 <1251> test report

You are 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

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