SARTURIUS

Service Datasheet

Minimum Weight Certificate

According to the European Pharmacopoeia



Benefits

- Reassurance during audits
- Achieving and maintaining compliance with the European Pharmacopoeia, Chapter 2.1.7.
- All binding tests are carried out
- Professional, easy-to-read certificates

Product Information

The European Pharmacopoeia (Ph. Eur.) contains standards for the quality control of medicinal products. Chapter 2.1.7. entitled "Balances for analytical purposes", which appears in Supplement 10.6 to the Ph. Eur., describes principles for the use of balances used in analytical procedures. In explicit terms, weighing procedures performed as part of tests designed to determine compliance with a monograph must be performed in accordance with the principles set forth in this chapter.

According to chapter 2.1.7. balances must be calibrated regularly and checked by conducting performance tests between calibrations to ensure compliance with predefined requirements.

Specification

- Balance test according to the requirements of the European Pharmacopoeia, Chapter 2.1.7.
- Documentation of the last calibration
- Repeatability is assessed by weighing one test weight 10 times
- Sensitivity testing with a suitable test weight
- Check whether the smallest customer net weight meets the requirements of the European Pharmacopoeia, Chapter 2.1.7.
- Determination of the minimum sample weight
- Creation of an easy-to-read 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
- USP <41> certificate

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

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