

December 2025

**Keywords:**

United States Pharmacopeia; USP; European Pharmacopeia; Ph.Eur; Japanese Pharmacopeia; JP; Chinese Pharmacopeia; ChP; Lab Weighing; Balances

# Updated requirements on balances for the pharmaceutical industry: Current status from USP, Ph.Eur., JP, ChP

**Dr. Julian Haller, Axel Taube**

Sartorius Lab Instruments GmbH & Co. KG, Otto-Brenner-Strasse 20, 37079 Goettingen, Germany

Correspondence

Email: [metrology@sartorius.com](mailto:metrology@sartorius.com)

## Introduction

The requirements for laboratory balances in the pharmaceutical industry have undergone significant evolutions and changes in recent years. Driven by a general need for clarification and the goal of international harmonization, the major pharmacopeias - United States Pharmacopeia (USP), European Pharmacopeia (Ph.Eur.), Japanese Pharmacopeia (JP), and Chinese Pharmacopeia (ChP) - have all fundamentally revised their chapters on balances and brought them into closer alignment.

At the heart of these changes is the recognition that the quality of analytical results depends critically on the reliability of the balances used. Where previously only general requirements for accuracy or calibration were set, today's regulations are much more precise and practical.

**Find out more:** [www.sartorius.com](http://www.sartorius.com)

## Current Revision Status and Regulatory Framework

**USP:** The mandatory chapter <41> “Balances” and the optional chapter <1251> “Weighing on an analytical balance” have both been recently revised. Both revisions were published in 07/2025 and will become official on 01.02.2026. The implementation of the USP is enforced by the Federal Food, Drug, and Cosmetic Act (FDCA).

**Ph.Eur.:** The chapter 2.1.7 “Balances for analytical purposes” that has been published initially in 07/2021 is currently under revision. Publication of the revised version is expected for 2026 so that it will become official end of 2026 or beginning of 2027. The implementation of the Ph. Eur. is enforced by the EU Directive 2001/83/EC for medicinal products for human use and the EU Regulation 2019/6 for veterinary medicines.

**JP:** A significantly revised version of chapter 9.62 “Measuring Instruments, Appliances” has been published in 06/2024 (together with 3 completely new general chapters on balances) and has to be implemented until 31.12.2025. The implementation of the JP is enforced by the Pharmaceutical and Medical Device Act (PMD Act, Act No. 145 of 1960).

**ChP:** Guideline 9032 “Guidelines for Analytical Balances and Weighing Specifications” has been published as a new guideline within the 2025 edition of the ChP in 03/2025 and came into force on 01.10.2025. The implementation of the ChP is enforced by the Drug Administration Law of the People's Republic of China.

### Scope of the Chapters

The current chapters of USP (Chapters <41> and <1251>), Ph.Eur. (Chapter 2.1.7), JP (Chapter 9.62), and ChP (Guideline 9032) all explicitly address balances used for analytical purposes. However, the detailed wording of the scopes slightly differs between the different pharmacopeias:

In the USP, the scope of chapter <41> actually has not been changed by the latest revision – it was and is applicable to those cases where a material according to a monograph must be “accurately weighed” (which is then denoted in the monograph by this particular wording). However, the latest revision tries to further clarify the scope by explicitly excluding balances used for manufacturing from the scope. Chapter <1251> is a recommendation anyway so it can be applied to any balance or not, but the latest revision explicitly mentions that the chapter can be applied to balances used in all analytical procedures in order to make them “fit for purpose” according to the (also optional) chapter <1058> “Analytical Instrument Qualification”.

For chapter 2.1.7 of the Ph.Eur., the scope is very similar but applicable cases are not as clearly identifiable via “signal

words” as in the USP. Generally, chapter 2.1.7 applies to all balances used for analytical purposes and in more detail to weighings that are performed as part of tests prescribed to establish compliance with a monograph of the Ph.Eur, while balances used for manufacturing or other purposes are explicitly excluded. With the upcoming revision however, presumably the applicability of the acceptance criteria of the performance checks will be further limited to tests with numerical limits and assays.

Concerning the JP, the chapter 9.62 is applicable to any testing of JP Drugs that are listed in the monographs of the JP. However, chapter <G1-6-182> “Concept of Weighing in the Japanese Pharmacopeia” limits the applicability to those cases, where metrological traceability is required and also gives qualification guidance for balances for any other case.

For guideline 9032 of the ChP, the scope is similar to that of USP chapter <41> - it generally applies to balances for analytical purposes used in weighing operations of pharmaceutical quality specifications. The signal words in such specifications that something must be “accurately weighed” directly indicates where guideline 9032 has to be fulfilled.

## Environmental Conditions

All mentioned Pharmacopeias emphasize that environmental conditions - such as temperature, humidity, air currents, vibration, static electricity, and electromagnetic fields - can significantly affect the performance of balances and the accuracy of weighing operations. The following points are consistently highlighted through all of them:

- Balances must be installed and operated in environments that minimize external influences.
- Environmental parameters should be controlled and monitored to ensure reliable and repeatable weighing results.
- Calibration and performance checks must be performed under conditions representative of actual use.

Although the detailed recommendations may slightly vary between the different Pharmacopeias (e.g. concerning the recommended range of relative air humidity), the following table can be taken as a general advice:

Parameter	Recommendation	Rationale
Temperature	Stable, avoid direct sunlight and heat/cold sources	Prevents drift and convection errors
Humidity	40 % to 60 % RH (ideally > 45 %)	Reduces static, prevents sample mass changes
Air currents	Minimize drafts, use enclosures	Prevents instability and measurement errors
Vibration	Use anti-vibration tables, avoid heavy equipment	Ensures repeatability and accuracy
Static Electricity	Use antistatic devices/containers, maintain humidity	Prevents weighing errors, especially for powders
Electromagnetic Fields	Avoid RF/magnetic sources, ground equipment	Prevents interference with electronic balances
Cleanliness	Keep area clean, avoid dust/corrosive vapors	Ensures reliable, contamination-free weighing

Furthermore, the following aspects will help users to ensure sufficiently good environmental conditions and reduce the risk of wrong measurement results:

- **Always follow the manufacturer's recommendations** for installation and operation.
- **Document and monitor environmental conditions** as part of your quality management system.
- **Train personnel** on the importance of environmental control for accurate weighing.
- **Use device features that reduce risks of measurement errors** due to environmental conditions like the IsoCal function, ionizers and cleaning apps



# Calibration and Metrological Traceability

A central element of all pharmacopeia chapters is the regular calibration of balances to ensure metrological traceability of measurement results to the International System of Units (SI).

Chapter <41> of the USP in the latest revision has put a stronger emphasis on this requirement – while in the previous version it was just required to use a balance that is calibrated over the operating range, the latest revision comprises a new dedicated section on calibrations, where it is clarified that a suitable calibration shall establish metrological traceability to the SI and hence must comprise measurement uncertainty of the results. It is further specified that calibrations must be performed periodically as well as before and after any significant intervention. Leveling the balance and internal adjustment are however explicitly mentioned as less significant operations which do not require calibrations before and after.

In chapter 2.1.7 of the Ph. Eur. and guideline 9032 of the ChP, a respective paragraph with a similar content already exists in the current version and in the JP, chapter <G1-6-182> gives background about metrological traceability and chapter <G1-7-182> about calibrations.

Despite small variations concerning the detailed recommendations and requirements in the different Pharmacopeias, the following Sartorius recommendations will suffice all of them:

- Let a competent (see box below) provider periodically calibrate the balance.
  - Calibration should be performed under conditions representative of actual use.
- The calibration interval should be determined based on the risk and the use of the balance.
- Calibration results should be assessed against user specifications, either on the calibration certificate or by the user.
- Calibration should be performed before and after any significant intervention like adjustment with an external weight, repair, opening of the balance's housing or moving the balance.
  - Leveling the balance and internal adjustment do not require calibrations before and after.



Accreditation according to ISO/IEC 17025 is generally accepted as a proof of competence and ensures that a recognized calibration procedure (like EURAMET Calibration Guide No. 18, ASTM E898 or JJF 1847) is applied and that a proper calibration certificate with measurement uncertainties is issued.

# Performance Checks

All considered Pharmacopeias require that performance checks of the Accuracy and the Repeatability are carried out by the user and that the frequency of the performance checks is based on the risk and the use of the balance.

The tests themselves have been harmonized so that the following applies to all Pharmacopeias:

## Performance Check of Accuracy

Sensitivity, linearity and eccentricity are considered the main contributors to accuracy and it is considered sufficient to periodically check sensitivity:

- A weight > 5 % of the balance's maximum capacity shall be used. The Sartorius recommendation is to use the biggest single piece weight below Max.
- A calibrated weight with an uncertainty of less than 1/3 of the acceptance criterion (0.05 %) must be used (see box below).
- Zero the balance, place the weight on the weighing pan and record the indication  $I$  once stable.
- Sensitivity is satisfactory, if:

$$\frac{|I - m|}{m} \leq 0.05 \%$$

Here  $m$  is the nominal weight or the conventional weighing value of the applied weight.

**Note:** In the recent revision of USP<41>, it has been added that in case of multiple range or multi-interval balances the lower test weight limit of 5 % refers to the maximum of the coarsest range and this will presumably be added to the upcoming revision of Ph.Eur. 2.1.7 as well. For JP and ChP, no respective detailed instructions for multiple range and multi-interval balances are given, but it can be assumed that the instructions from USP and Ph.Eur. may be applied there as well.

Furthermore, it has been made clearer in the recent revision of the USP that the acceptance criterion for accuracy is 0.10 % and that is sufficient to test sensitivity against an acceptance criterion of 0.05 % to achieve that. The same differentiation is already made in the current version of the Ph.Eur. as well as in the respective new chapters of JP and ChP.



As mentioned, a calibrated weight with an uncertainty of less than 1/3 of the acceptance criterion of 0.05 % must be used for the sensitivity check.

This is always fulfilled when the nominal weight of weights of class  $F_1$  or better according to OIML R111-1:2004, JIS B 7609:2008 or JJG 99-2022 (or class 3 or better according to ASTM E617) above 500 mg is used.

## Performance Check of Repeatability

All mentioned Pharmacopeias require periodical performance checks of the repeatability as follows:

- A weight  $\leq 5\%$  of the balance's maximum capacity shall be used, but if that yields a weight below 100 mg, 100 mg shall be used instead. The Sartorius recommendation is to use the biggest single piece weight below 5% of Max.
- Zero the balance, place the weight at the center of the weighing pan, and record the indication / once stable. Repeat the whole procedure at least 10 times (including the zeroing of the balance before each repetition).
- Calculate the standard deviation  $s$  of the indications as:

$$s = \sqrt{\frac{1}{N-1} \cdot \sum_{i=1}^N (I_i - \bar{I})^2}$$

where

$$\bar{I} = \frac{1}{N} \cdot \sum_{i=1}^N I_i$$

is the mean of the indications.

- If  $s < d$  ( $d$ : resolution | scale interval of the balance), replace  $s$  with a lower limit value  $s = 0.41 \cdot d$ .
- Repeatability is satisfactory, if

$$\frac{2 \cdot s}{m_{\text{snw}}} \leq 0.10 \%$$

where  $m_{\text{snw}}$  is the smallest net weight that a user wants to weigh on the balance (see next section for details).

**Note:** Also for repeatability it has been clarified in the recent revision of USP<41> that in case of multiple range or multi-interval balances the upper test weight limit of 5% refers to the maximum of the coarsest range and that for multi-interval balances the test weight should be in the finest partial weighing range. The same will presumably be added to the upcoming revision of Ph.Eur. 2.1.7 and can likely be considered acceptable for JP and CHP as well.

Furthermore, it is now mentioned in USP <41> that for multiple range balances the test shall be performed in each range that is used in routine operation.

## Minimum Weight, Smallest Net Weight and Safety Factor

The two different terms "minimum weight" ( $m_{\text{min}}$ ) and "smallest net weight" ( $m_{\text{snw}}$ ) already existed in previous versions of the USP chapters <41> and <1251> and in the current version of chapter 2.1.7 of the Ph.Eur.. However, the difference between the two values was supposedly not clear for all users and substantial effort has been made in the current revisions of chapters <41> and <1251> of the USP and will presumably also be made in the upcoming revision of Ph.Eur. 2.1.7 to clarify the difference:

The "**smallest net weight**" ( $m_{\text{snw}}$ ) is a value that has to be defined by the user. It is the smallest sample quantity that shall be weighed on the balance and should usually be defined only once and then not be changed anymore (unless this happens in a well-documented way, e.g. when it turns out that for a particular balance under the given conditions the risk is considered too high that it remains achievable for the future).

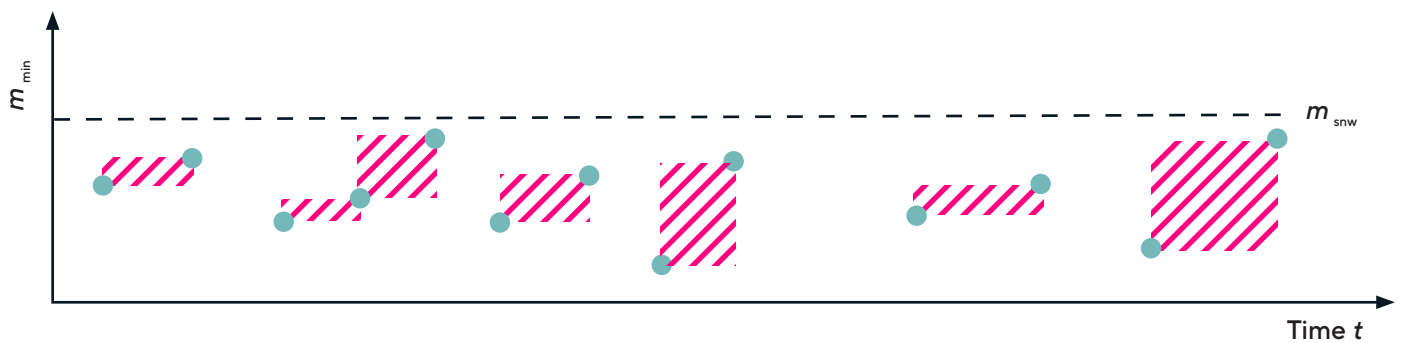
The "**minimum weight**" ( $m_{\text{min}}$ ) however is the (temporary) result of each performance check. It can be derived from reshaping the repeatability criterion on the left to  $m_{\text{min}} \geq (2 \cdot s) / 0.10\%$  which yields the smallest value that just fulfills the criterion. Minimum weight is thus calculated as  $m_{\text{min}} = 2000 \cdot s$  (with  $s$  being replaced by the lower limit value  $s = 0.41 \cdot d$  if  $s < d$  has been measured). As the minimum weight might change after each performance check, it is explicitly not advised to use this value as the smallest allowed weighing value.

**Note:** Both smallest net weight and minimum weight explicitly refer to *net* weighing values – that means that using a tare load like a vessel to exceed the smallest net weight (and then subtracting the weight of the vessel) is not permissible. This was already the case in previous versions of the USP and still remains valid and important.

The concept of a "**safety factor**" ( $SF$ ) as the ratio between the smallest net weight and the minimum weight has been introduced in the current revision of USP<1251> as well as in the ChP and it might probably also be introduced in the upcoming revision of Ph.Eur. 2.1.7. It is however not mandatory.



The below picture schematically shows results of minimum weight determinations (turquoise dots) over time and explains why adapting the smallest net weight to the determined minimum weight after each performance check is not recommended: whenever a minimum weight is determined at a performance check that is bigger than the one determined at the previous performance check (and down to which weighings were performed) all weighings between these two values from the respective timespan (magenta shaded areas) have to be questioned as it cannot be ensured that the respective criterion of 0.10 % was met. If instead the smallest net weight would have been defined once in the beginning (dashed black line) and weighings on this balance are allowed only above this value, the different minimum weight values determined over time rather serve as confirmations that the criterion was met all the time. Some of the performance checks yielded  $m_{\min}$  values that were somewhat close to  $m_{\text{snw}}$  – i.e. there is a certain probability that before or after this performance check the criterion was exceeded. In order to ensure that also between performance checks the criterion is met with a sufficiently high probability, an additional safety factor can thus give additional security.



# Recommendations and Supporting Assets

## Sartorius recommendations how to comply with requirements from Pharmacopeias:

- Check, which balance falls under the scope of which Pharmacopeia (→see Section "Scope of the chapters" above)
- Check environmental conditions and improve them if necessary (→see Section "Environmental Conditions" above and [1])
- Check the availability of device features to support you and use them (→IsoCal function, ionizers, cleaning app,...)
- Define a smallest net weight for each balance and possibly a safety factor (→see [5], [6] and [10])
- Define intervals for performance checks based on a risk analysis (→see [10])
- Properly train persons on performance checks and document the results (→see [15],[16] and [27])
- Define intervals for calibrations by a competent provider (→see [7] and [10])
- Define tolerances for calibrations and have them assessed on the calibration certificate (→see [3], [9] and [10])
- Let the competent provider perform a performance check in addition to the calibration as an independent confirmation (→see [18]-[21])

## Sartorius supporting assets:

- White Paper Bundle:  
Sartorius has published numerous White Papers and Application Notes to support users in compliant weighing. Particularly, a White Paper Bundle "Best Practice Guide: Lab Weighing" has been published in the last years, where the following White Papers can support users to achieve compliance with requirements from Pharmacopeias:
  1. [Reliable Weighing Results](#) - Proper Handling of Laboratory Balances and Correct Handling of Samples
  2. [Weighing in Legal Metrology](#) - Use and Testing of Laboratory Balances in Legally Regulated Environments Weighing
  3. [Calibration guideline EURAMET cg-18](#) - specifications, options and implementation of the guideline by Sartorius
  4. [Sartorius Balance Test Report](#) - Testing and Evaluating Balances Against Different Tolerance Requirements
  5. [Minimum Sample Weights According to USP <41>, OIML R76 and EURAMET cg-18](#)
  6. [Use of Laboratory Balances in the Pharmaceutical Industry](#)
  7. [Calibration Certificates From Accredited Providers](#) - What Benefits Do Our Accreditations Offer the User?
  8. [Handling Test Weights - Sensible Selection and Correct Handling of Test Weights](#)

9. [Sartorius Calibration Certificate for Weighing Instruments According to EURAMET cg-18](#) Explained Step-by-Step
10. [Test Intervals and Tolerances](#)

- Generic OPs  
To make it easier for users to perform and document performance checks in a harmonized and user-independent manner, Sartorius has published "Generic Operating Procedures." These can be adopted directly by users or adapted to their specific needs. Currently, the following Generic Operating Procedures are available:
  11. [One-Point Calibration](#)
  12. Sensitivity Test
  13. [Repeatability Test](#)
  14. [Eccentricity Test](#)
  15. [Performance Test according to USP <41>](#)
  16. [Performance Test according to Ph. Eur. 2.1.7](#)
- Sartorius Service Certificates  
Sartorius Service offers a variety of certificates/reports ensuring reliable and reproducible measurement results as well as professional, traceable and audit-secure documentation:
  17. [Calibration certificate with ISO | IEC 17025 accreditation](#)
  18. [USP <41> Certificate](#)
  19. [Ph. Eur. Certificate](#)
  20. JP 9.62 certificate
  21. [USP <1251> test report](#)
  22. [Balance test report](#)
- Q App | Pharma Package QP1
  23. [User Management \(QAPP100\)](#)
  24. [Electronic Signature \(QAPP101\)](#)
  25. [Audit Trail \(QAPP102\)](#)
  26. [minUSP \(QAPP103\)](#)
  27. [USP Advanced \(QAPP104\)](#)
  28. [Measurement Uncertainty \(QAPP105\)](#)
  29. [User Calibration \(QAPP106\)](#)

## Conclusion

Today's requirements for balances in the pharmaceutical industry are clear, practical, and internationally harmonized. Those who understand and implement the current standards of the major pharmacopeias lay the foundation for reliable, audit-proof, and internationally recognized analytical results.

Sartorius strives to support users on their way with reliable high-quality weighing instruments, supporting assets and clear recommendations.

**Germany**

Sartorius Lab Instruments GmbH & Co. KG  
Otto-Brenner-Strasse 20  
37079 Goettingen  
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](http://www.sartorius.com)