Japanese Pharmacopeia Chapter 9.62

Measuring Instruments, Appliances

Frequently Asked Questions

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1. What are the requirements for balances and weights as outlined in the new Chapter 9.62 “Measuring Instruments, Appliances“?

With the recent publication of “Supplement II to the Japanese Pharmacopoeia 18th Edition,” several chapters on balances and weighing have been added or revised. Three new chapters are now part of the “General Information” section.

Chapter 9.62, “Measuring Instruments, Appliances,” has undergone a complete revision. Previously, it only defined and classified “Chemical balances,” “Semi-micro balances,” “Micro balances,” and “Ultra-micro balances ,” and required the use of calibrated weights. The new version includes detailed requirements for balances and weights:

Requirement	Chapter 9.62 Requirement	Sartorius Recommendation
Calibration of balances	Calibrate balances to ensure traceability to the International System of Units (SI).	Calibrate all balances in regulated branches periodically using an accredited provider.
Repeatability of balances	**Define the "smallest net weight (m_{snw})" to be weighed on the balance.** **Periodically check that the "minimum weight (m_{min})" is smaller than m_{snw}.** **The minimum weight (m_{min}) is determined using the formula:** $m_{min} = 2000 \times s$ (or $m_{min} = 2000 \times 0.41 \times d$, if $s < 0.41 \times d$) where: s is the standard deviation of a repeatability measurement with at least 10 repetitions performed with a weight of about 5 % of the maximum capacity (Max) and at least 100 mg. d is the actual scale interval of the balance. This requirement aligns with the respective requirements in USP <41>, USP <1251>, and Ph.Eur. 2.1.7. Note that there are small differences concerning the required test load. However, using the largest single piece test load ≤ 5 % of Max aligns with the standards set by all Pharmacopoeias.	Periodically check and document the repeatability at risk-based intervals. Additionally, have an independent external provider check and document it at longer intervals. Learn More
Accuracy (trueness) of balances	Periodically check to ensure that the sensitivity error is less than or equal to 0.05 %. This condition is satisfied if: $\frac{\lvert I - m \rvert}{m} \times 100 \leq 0.05$ where: m is the nominal or conventional mass of a test load between 5 % and 100 % of the maximum capacity (Max). I is the indication of the balance when placing this test load on the balance. This requirement aligns with the standards set by all Pharmacopoeias.	Routinely check and document the repeatability at risk-based intervals. Additionally, have an independent external provider check and document it at longer intervals. Learn More
Calibration of weights	Calibrate weights used for sensitivity checks to ensure traceability to the SI and that they have an appropriate accuracy class for this purpose. Chapter G1-7-182 specifies that weights are suitable for sensitivity checks when their Maximum Permissible Error (MPE) (using the nominal value as m) or calibration uncertainty (using the conventional value as m) is no more than ⅓ of the test specification. This requirement aligns with USP <41> and Ph.Eur. 2.1.7 and is met when using class F1 weights with nominal values ≥ 500 mg.	Periodically calibrate all weights used for performance checks in regulated branches by an accredited provider. Sartorius uses only weights that are traceable to the SI and recalibrated periodically for performance checks according to Chapter 9.62.

2. When should I follow Chapter 9.62 and when should I follow Chapter <G1-6-182>?

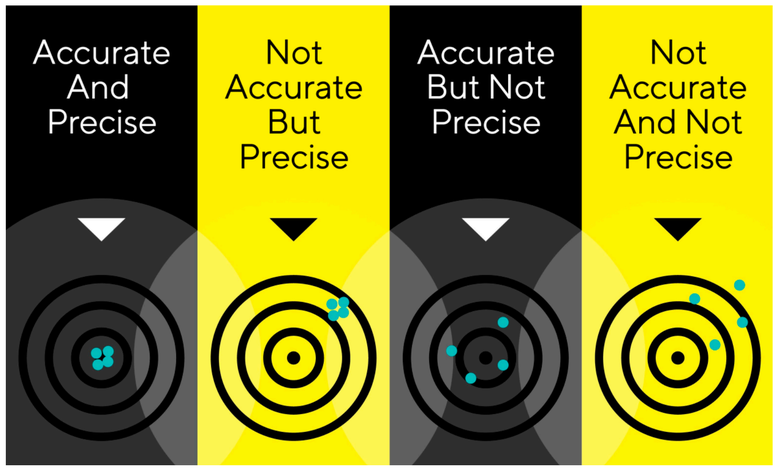
Follow Chapter 9.62 when weighing results must be metrologically traceable to the SI. Apply Chapter G1-6-182 only when results do not necessarily need to be traceable to the SI.

3. What is the main difference between Chapter 9.62 and Chapter <G1-6-182> concerning the required balances?

Chapter <G1-6-182> states that the scale interval should be one digit finer than the amount to be weighed. For example, when weighing 15 mg, an analytical balance with a scale interval of 0.1 mg would be sufficient.

In contrast, Chapter 9.62 requires users to define a "desired smallest net weight" to be weighed on the balance. Due to the concept of "minimum weight," the scale interval of the balance must be at least 820 times smaller. For instance, when weighing 15 mg, an analytical balance with a scale interval of 0.1 mg is no longer sufficient; instead, a semi-micro balance with a scale interval of 0.01 mg is required.

4. What do precision, accuracy, sensitivity, and linearity mean?



- **Precision** is the "closeness of agreement between indications obtained by replicate measurements" and can be determined by a repeatability measurement.
- **Accuracy** is the "closeness of agreement between a measured value and the corresponding true value". Accuracy cannot be directly measured.
- **Sensitivity** contributes to accuracy. According to chapter 9.62, it can be measured as the difference between the indication for weighing of an appropriate test load and the true weight of the test load (given by its nominal or conventional weight value), divided by the true weight.
- **Linearity** is the proportionality between applied loads and the corresponding indications over the complete weighing range (e.g. in USP<1251> or Sartorius data sheets). However, Chapter G1-7-182 defines it slightly differently as the "deviation between the mass value and the indicated value over the entire specification range." Note that these two definitions are not directly comparable.

5. What operational checks and cleaning procedures are recommended in Chapter <G1-8-182> for the proper use of balances?

Chapter <G1-8-182> “Installation Environment, Basic Handling Method, and Precautions for Weighing of a Balance” provides several useful explanations and recommendations for the correct use of weighing instruments. It covers topics such as the installation site, operational checks, cleaning procedures, and external factors that may affect weighing results, including temperature differences, air drafts, and static electricity.

6. Does the new chapter impact my company’s operations?

The Japanese Pharmacopeia serves as the legally binding standard for all pharmaceutical companies that market their products in Japan.
This regulation is not only pertinent to Japanese pharmaceutical firms, but also to any manufacturers of medicines or pharmaceutical substances who export to the Japanese market.

7. Is it possible to weigh smaller samples on the balance if the tare weight exceeds the minimum weight?

The tare vessel’s mass is not included in the minimum sample weight. The minimum weight requirement applies to net loads across the entire weighing range of the balance, regardless of the tare load. Each sample’s net weight must meet or exceed the minimum weight, even when using a tare vessel.

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