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The New USP, Chapter 41 "Balances"

After nearly 20 years, Chapter 41 of the USP has been significantly revised. A global team of experts drafted the new version, which was recently approved for release by the USP. Currently the revised Chapter 41 can be accessed in the online forum of the USP, the USP PF.

As soon as the printed version of USP is available, the updated Chapter 41 will also be binding. The transitional period is currently in effect during which users may proceed according to either the old or the new USP.

Below is an excerpt of the new Chapter 41:

41 Balances
This chapter states the requirements for balances used for materials that must be accurately weighed (see General Notices, 8.20). Unless otherwise specified, when substances must be "accurately weighed", the weighing shall be performed using a balance that is calibrated over the operating range and meets the requirements defined for repeatability and accuracy. For balances used for other applications, the balance repeatability and accuracy should be commensurate with the requirements for its use. For discussion of the theoretical basis of these requirements, see general information chapter Weighing on an Analytical Balance 1251, which may be a helpful – but not mandatory – resource.

Repeatability
*Repeatability is assessed by weighing one test weight NLT 10 times. [**Note** – The test weight must be within the balance's capacity, but the weight need not be calibrated. Because repeatability is virtually independent of sample mass within the balance's capacity, use of a small test weight, which may be difficult to handle, is not required.] Repeatability is satisfactory if two times the standard deviation of the weighed value, divided by the nominal value of the weight used, does not exceed 0.10%. If the standard deviation obtained is less than 0.41d, where d is the scale interval, replace this standard deviation with 0.41d. In this case, repeatability is satisfactory if two times 0.41d, divided by the nominal value of the weight used, does not exceed 0.10%.*

Accuracy
*The accuracy of a balance is satisfactory if its weighing value, when tested with suitable weights, is within 0.10% of the test weight value. A test weight is suitable if it has a mass between 5% and 100% of the balance's capacity. Its maximum permissible error (mpe), or alternatively its calibration uncertainty, shall be NMT one-third of the applied test limit of the accuracy test. [**Note** – Applicable standards are the following: ASTM E617 (available from http://www.astm.org) and OIML R 111 (available from http://www.oiml.org).]*

Interpretation

In the new Chapter 41, the minimum sample weight is no longer mentioned. Rather, it is necessary to determine the operating range of a balance. This range is limited above and below by the maximum capacity of the balance and begins at the point at which the balance's repeatability is less than or equal to 0.10%.

Repeatability
The new USP requires that the repeatability of a balance be determined based on at least 10 comparable weighed values. For this test, Sartorius recommends using one weight close to approximately half of the maximum capacity of the particular balance (in other words, for a 200 g analytical balance, you need to use a weight of 100 g). The USP states that it is not necessary to use a small test weight to assess the repeatability. Sartorius recommends performing a repeatability test at approximately half of a balance's maximum capacity in order to combine the repeatability test and the accuracy test (the accuracy test is described later in this document).

Determine the standard deviation from 10 comparable weighed values and multiply these by an expansion factor of 2 (in other words, $2 \times$ the std. deviation). If this value is multiplied by 1,000, this will yield the starting point of the operating range for a particular balance.

If a standard deviation less than 0.41 digit is obtained (in other words, 0.041 mg for an analytical balance with a readability of 0.1 mg), this must be replaced by 0.41 d so that the smallest possible starting point of an operating range of up to 820 d (2 * 0.41 * 1,000) is obtained. For an analytical balance with a readability of 0.1 mg, this means the starting point yielded is 82 mg.

Accuracy

In addition to the repeatability, the accuracy of a balance must now also be determined. The USP requires a simple test. The accuracy of a balance is sufficient if the weighed value displayed does not differ by more than 0.10% of the conventional mass of the weight placed on the balance. The conventional mass consists of the nominal value of the weight used and the actual difference given on its respective calibration certificate. For this test, only weights may be used that have a maximum permissible error (mpe) of no more than $\frac{1}{3}$ of 0.10%; in other words, 0.03%. This requirement merely signifies that it is not mandatory to use a high-class E2 weight. In most cases, it is sufficient to use class F weights. A further requirement is that the accuracy must be determined using a weight with a mass value between 5% and 100% of the capacity of the particular balance (for a 200 g analytical balance, this means you need to use a weight with a mass of between 10 g and 200 g).

As already explained above, it is possible to combine both tests (repeatability and accuracy) if a weight corresponding to half of the maximum capacity of a balance is used to determine the repeatability. One of the 10 weighed values of this repeatability test can be used to determine the balance's accuracy. This procedure ensures maximum efficiency in determining the required specifications.

Chapter 1251

In addition to the mandatory Chapter 41 requirements, the respective Chapter 1251 has been significantly revised. This chapter is only a recommendation and is not mandatory. All procedures and methods described in Chapter 1251 can also be modified.

Overview of the Changes

Chapter 41	Old	New
Scope of validity	Applies only to assays of substances	Applies to all sample weights
	Determination of the minimum sample weight	Determination of the operating range
Repeatability (around the starting point)		
Repeatability tolerance	0.1 (49) %	0.10%
Expansion factor K	3	2
Number of weighing values for the repeatability test	10	10
Acceptance criterion	3 × std. dev. /m ≤ 0.1%	2 × std. dev./m ≤ 0.10%
Smallest possible sample weight | lowest starting point	1,000 d	820 d
Accuracy		
Tolerance	None specified	≤ 0.10%
Test weight	None specified	Between 5% and 100% of the balance's capacity