



USP Modifications in Chapter 41 and 1251

After its initial modification to Chapter 41 and 1251 in December 2013, the USP (U.S. Pharmacopeial Convention) is continually refining its requirements for balance calibrations. A balance calibration is a check to verify that the balance's weight display matches the nominal weight value. Many people interpret this to be calibration with adjustment; however, a calibration is a verification not an adjustment.

The USP requirements state that calibrations are applicable when substances must be "accurately weighed." Balance weighing should be performed using calibrated equipment that has been calibrated at capacity and tested for repeatability and accuracy. The balance should also be tested at a minimum weighing point and not used below that point.

Repeatability of the balance is tested by weighing one test weight 10 times. The weight used is within the balance's operating range. The weight does not need to meet any calibration requirements as the weight is used to check that the readings are repeatable. The results are acceptable if "two times the standard deviation of the weighed value, divided by the desired smallest net weight (i.e. smallest net weight that the users plan to use on that balance) does not exceed 0.10%."

Accuracy is acceptable if the balance's weighing value is within 0.10% of the test weight value. The accuracy test weight is a calibrated weight with maximum permissible error (mpe), or its uncertainty, of one-third of the applied test limit of the accuracy test.

In order to help laboratories and businesses comply with these updated guidelines, Rice Lake offers Essential Weights™. Designed with convenience in mind without sacrificing precision, Essential Weights are sets of stainless steel test weights specifically tailored to your balance.

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References to Chapter 41 and 1251:

Chapter 41	Previous	Updated
Scope	Defines “the requirement for balances used to weigh analytes for quantitative measures”	Same scope with new language for added clarity
Calibrated balance	Not specified	All balances must always be calibrated
Number of balance tests	1 - repeatability	2- repeatability and accuracy
Test 1 - Repeatability		
Limit of repeatability test	≤ 0.1%	≤ 0.10%
Expansion factor	3	2
Total replicate weighing procedures	10	10
Acceptance criterion (RP)	3*s/m ≤ 0.1%	2*s/m ≤ 0.10%
Other criterion	N/A	If the repeatability obtained is smaller than 0.41 d, where d is the scale interval, replace the standard deviation with 0.41 d
Test 2 - Accuracy		
Limit of accuracy test	N/A	≤ 0.10%
Test weights	N/A	Between 5% and 100% of the balance capacity
Chapter 1251	Previous	Updated
Scope	Applies to “all analytical procedures”	No change
Balance test		
Performance test	Drift check to be performed daily	Risk analysis determines the frequency of any test
Built-in weights	N/A	Checks can be partially replaced using automatic or manually triggered adjustment by means of built-in weight
Minimum weight	N/A	The minimum weight applies to the sample weight, not the tare or gross weight
Calculation of minimum weight	N/A	Derived by using a test weight “up to a few percent of the balance capacity”: $m = 2000*s$
Repeatability test	N/A	As repeatability fluctuates, weighing should be performed at larger values than the minimum weight

Complete, up-to-date information can be found at www.usp.org.

The new minimum weight requirements establish guidelines for operators to use the balances within a certain range. This is calculated from the repeatability test and begins at a point where the balance’s repeatability is less than or equal to 0.10%. The specification states that the minimum weighing range will be 0.41 d (or the larger repeatability test result).

The impact of these requirements establishes best practices for balance applications. Balances that may have been purchased for applications based on specification sheets may not perform to those specifications in real-life applications. With these requirements, balances will be calibrated (checked) and a routine system established to make sure the balance meets application requirements.



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