



Troemner Cal-Paks™ and USP 41

On December 1, 2013 the latest revisions to United States Pharmacopeia (USP) General Chapter 41 Balances became official. The goal of the revision is to ensure weighing accuracy that reflects current weighing methods.

The revised USP-41 now has two mandatory critical components:

- Repeatability
- Accuracy

Repeatability

The revised standard does not dictate the minimum weight that can be used, but rather how the user can determine the operating range of the balance.

The balance's operating range is determined from the repeatability of the balance at a nominal value. This is a new requirement that can be performed by the user during balance calibration. During calibration, the weight used will be the maximum weight for that balance. For example, consider a 220g balance where a 200g calibration weight will be used to perform 10 replicate weighings for the repeatability test. If the repeatability test is performed in-house, then the weight used is the lowest nominal value in the balance's operating range.

Example:

5g balance with readability (d) of 0.001mg
Weight operating range is 5g - ?

The formula is:

$$2 * \text{repeatability} * 1000 \leq 0.10\%$$

Note: The old requirement was 0.1% and with rounding the value could be as large as 0.149%.

The specification of the balance for repeatability using a 5g weight is 0.0008mg under proper conditions. When we apply the formula we have:

$$2 * 0.0008 * 1000 = 1.6\text{mg}$$

Therefore our weight operating range = 5g – 1.6mg

Testing repeatability using a 1mg weight, the repeatability will be 5g – 1mg. The minimum weight will have a repeatability of approximately 0.000mg and this is statistically improbable, therefore USP states the minimum repeatability will be 0.41 of a digit.

Example:

5g balance with readability (d) of 0.001mg
Weight operating range is 5g - ?

Using 1mg weight and applying the formula we have:

$$2 * 0.00041 * 1000 = 0.8\text{mg}$$

Therefore, our weight operating range = 5g – 0.8mg



Accuracy

Accuracy still defines the test weight that can be used to test the balance. The weight must be within 100% - 5% of the capacity of the balance, and the test weight's tolerance must be 0.10% of the nominal value. Additionally, the weight uncertainty must not exceed 1/3 of the tolerance. Therefore all test weights must have a traceable calibration report that lists the correction and uncertainty values.

Example:

5g – 1mg balance with a readability of 0.001mg
Test weight range 5g – 250mg to meet the 100% - 5% requirement
Accuracy tolerance of a 5g test weight is 0.10% of 5g = 5mg
ASTM Class 4 tolerance for 5g weight = 1.2mg
Uncertainty \leq 0.40mg

Accuracy tolerance of a 500mg test weight is 0.10% of 500mg = 0.5mg
ASTM Class 4 tolerance for 500mg weight = 0.16mg
Uncertainty \leq 0.04mg

Cal-Paks™

Troemner Cal-Paks™ are the ideal weight sets to meet the required revisions to USP 41. Each Cal-Pak™ set contains (3) high quality, precision weights which can be used with all balance manufacturers' makes and models. The weights supplied are the balance manufacturers' recommended calibration weight, 10% of the calibration weight, and the repeatability test weight as determined by the balance's readability and expected standard deviation under normal conditions. Troemner Cal-Pak™ components are linked through the use of a unique serial number. You can trace your individual weights to the appropriate NVLAP traceable calibration certificate and master carrying case. The precision weights in your Cal-Pak™ are traceable to the international kg standard through an exacting series of traceable measurements that provide an accurate value for each weight with an uncertainty that exceeds the requirements of USP.