



TROEMNER

Technical Paper

Introducing...Troemner Cal-Paks™
Measuring Accuracy of Weights and Balances Using Troemner Cal-Paks™
for Compliance with USP 41 and ASTM E898



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All research scientists, technicians, metrologists, and quality assurance managers worldwide can agree that the accuracy and precision of balances for tests and assays is of utmost importance. To maintain the integrity of a balance, it must be calibrated at regular intervals using precision external weights of the recommended min, mid, and max-range. USP 41 and ASTM E898 provide the accepted standards and testing methods for maintaining accuracy of weights and balances. Troemner's Cal-Paks™ consist of the high quality precision mass standards with low measurement uncertainties, conveniently packaged to insure accuracy you need and comply with both USP 41 and ASTM E898.

What is USP 41?

United States Pharmacopoeia (USP) is an independent, non-profit, science-based health organization that develops and disseminates the quality standards and information for producing and delivering medicines, healthcare and related products and practices to benefit public health. USP is the official authority charged with setting the standards of manufacturing and sales of all pharmacological products made or sold in the USA. Federal law in the USA requires that all prescription and over-the-counter medicines available must meet the USP public standards. The USP standards are also recognized and used worldwide in over 130 countries.

USP 41 addresses weights and balances. It describes the method and variances for periodic calibration of balances:

“Pharmacopoeial tests and assays require the use of balances that vary in capacity, sensitivity, and reproducibility. The accuracy needed for a weighing dictates the type of balance and the class of weights required for that weighing. Where substances are to be “accurately weighed,” the weighing is to be performed so as to limit the error to not more than 0.1%. For example, a quantity of 50mg is to be weighed so that the error does not exceed 50 µg. A balance should be chosen such that the value of three times the standard deviation of the reproducibility of the instrument, divided by the amount to be weighed, does not exceed 0.001.”

What is ASTM E898?

ASTM International (originally American Society for Testing and Materials) has provided technical standards for over a century and is a trusted source world-wide. Its technical standards for materials, products, systems, and services are used to guide the design, manufacturing, and trade throughout the world. Its standards reflect the work of more than 30,000 ASTM members from over 120 countries, representing producers, users, consumers, government and academia.

ASTM E898 is the standard method of testing top-loading, direct-reading laboratory scales and balances, ranging in capacity from a few grams to several kilograms, and with resolution from 1/1000 of capacity to 1/1000000 or more. The method of determining the precision and accuracy of weighing instruments brings to light both the strengths and weaknesses of the instrument, including repeatability, reproducibility, precision, accuracy and linearity.

This ASTM standard recommends using not only a minimum and maximum weight calibration, but also a mid-weight that is 10% of the maximum weight.

How does Troemner Cal-Pak™ satisfy USP 41 and ASTM E898 requirements?

Troemner Cal-Paks™ meet all of your regulatory and auditory needs, including both USP 41 and ASTM E898. In addition, the regulatory and auditory requirements for ISO, FDA, GMP, GLP, DOD, ANSI/NCCL Z540-1, 10CFR, and 21CFR are satisfied by correct use of the Troemner Cal-Paks™. You can define accuracy and precision correctly during calibration by testing the balance at the maximum, the mid-range (10% of maximum), and minimum weights.

Troemner Cal-Paks™ give you:

- Calibration consistency
- Alloy 8 advantage
- Low uncertainties

Each Troemner Cal-Pak™ includes:

- Three (3) high precision weights:
 - Manufacturer's recommended calibration weight
 - 10% calibration weight
 - Minimum weight as determined by the balance's readability and expected standard deviation under normal conditions as recommended by USP 41.

The weights are ASTM Alloy 8 of either Class 0 or Class 1, which can be used with all manufacturers' makes and models. Troemner Cal-Pak™ components and carrying case are linked through the use of a unique serial number. You can trace your individual weights to the appropriate NVLAP Certificate and master carrying case.

- Your Cal-Pak™ includes a USB Flash Drive that contains your electronic NVLAP Certificate.
- The weights are supplied in a rugged polypropylene case with each individual weight in its own high quality polycarbonate case.
- Troemner Cal-Paks™ include accessories for proper handling and care of the weights.
- Troemner Cal-Paks™ are manufactured in the USA.

Table 1 – USP 41 Recommended Class and Tolerances

Denomination	0.1% Nominal mg	Class 0 Tolerance mg	Class 1 Tolerance mg	Class 2 Tolerance mg	Class 3 Tolerance mg	Class 4 Tolerance mg
100g	100		0.25	0.50	1.0	2.0
50g	50		0.12	0.25	0.60	1.2
30g	30		0.074	0.15	0.45	0.90
20g	20		0.074	0.10	0.35	0.70
10g	10		0.050	0.074	0.25	0.50
5g	5		0.034	0.054	0.18	0.36
3g	3		0.034	0.054	0.15	0.30
2g	2		0.034	0.054	0.13	0.26
1g	1		0.034	0.054	0.10	0.20
500mg	0.5	0.005	0.010	0.025	0.08	0.16
300mg	0.3	0.005	0.010	0.025	0.07	0.14
200mg	0.2	0.005	0.010	0.025	0.06	0.12
100mg	0.1	0.005	0.010	0.025	0.05	
50mg	0.05	0.005	0.010	0.014		
30mg	0.03	0.005	0.010	0.014		
20mg	0.02	0.005	0.010			
10mg	0.01	0.005				
5mg	0.005	0.005				
3mg	0.003	0.005				
2mg	0.002	0.005				
1mg	0.001	0.005				

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