The New United States Pharmacopeia (USP) Chapter 41
It’s easier than you think!
The new USP Chapter 41

Area of Application

Chapter 41 will solely apply to balances and not to weights anymore.

So far, the USP Chapter 41 was named “Weights and Balances”. With its new release in December 2013 the name will change to “Balances” only, which indicates its major scope. Likewise, Chapter 41 does not refer to minimum sample weights any longer. Instead, it newly defines the terms Repeatability and Accuracy. Both concepts are of crucial importance as they together define the Operating Range of a balance.

Recommendation

If you follow our recommendations on how to perform the repeatability and accuracy testing, you will be compliant with the new requirements of Chapter 41 – it’s really that easy!
Repeatability

According to the new USP Chapter 41 “repeatability” defines the starting point of a balance’s operating range.

How to calculate it?

- Perform 10 measurements with the exact same weight
- Calculate $2 \times \text{Standard Deviation (SD)} / \text{nominal value} \leq 0.10\%$
- Calculate the starting point of the Operating Range: $2 \times \text{SD} \times 1000$
- If SD < 0.41 digits, replace it by 0.41 digits.

What does this mean?

The higher you go in a balance’s weighing range, the more accurate it is, relatively. Your results will be in a similar range as with the old determination parameters, so you should not expect any significant changes.
**Accuracy**

Chapter 41 defines the process requirements to check the accuracy of a balance.

In order to test a balance’s accuracy, Chapter 41 requires you to use a test weight which has a mass of 5 % to 100 % of the balance’s maximum capacity.

**How to calculate it?**

- The measurement uncertainty of the weight must be $\leq 1/3$ of 0.10 %
- Take one measurement with a mass of 5 % to 100 % of the balance’s capacity
- The deviation of the measured value should be $\leq 0.10$ % of the weight value

**What does this mean?**

The USP describes the quality of the weights to be used for this test. This means you must use a calibrated weight to prove the uncertainty of that weight. However, you do not need to use higher class weights. OIML Class F1 or F2 weights are usually sufficient.
USP Chapter 1251

The USP Chapter on “Weighing on an Analytical Balance” is not mandatory!

The most important piece of information on the USP Chapter 1251 on “Weighing on an Analytical Balance” is that it is only a recommendation – you are not required to follow the procedures described in this chapter.

Chapter 1251 describes:

- Balance qualification
- Balance calibration
- Risk analysis (risk-based approach)
### Overview of the Changes

<table>
<thead>
<tr>
<th>Chapter 41</th>
<th>Old</th>
<th>New</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Area of Application</strong></td>
<td>only valid for assays</td>
<td>only valid for accurate measurements</td>
</tr>
<tr>
<td>determination of minimum sample weight</td>
<td></td>
<td>determination of a balance’s operating range</td>
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</tbody>
</table>

### Repeatability

<table>
<thead>
<tr>
<th></th>
<th>Old</th>
<th>New</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Tolerance</strong></td>
<td>0.1 (%9)</td>
<td>0.10 %</td>
</tr>
<tr>
<td><strong>Expansion Factor</strong></td>
<td>3</td>
<td>2</td>
</tr>
<tr>
<td><strong>Number of Measurements for Test</strong></td>
<td>10</td>
<td>10</td>
</tr>
<tr>
<td><strong>Acceptance Criterion</strong></td>
<td>3 x sd / m ≤ 0.1 %</td>
<td>2 x sd / m ≤ 0.10 %</td>
</tr>
<tr>
<td>**Smallest possible sample weight</td>
<td>Lowest starting point**</td>
<td>1000 d</td>
</tr>
</tbody>
</table>

### Accuracy

<table>
<thead>
<tr>
<th></th>
<th>Old</th>
<th>New</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Tolerance</strong></td>
<td>n.a.</td>
<td>≤ 0.10 %</td>
</tr>
<tr>
<td><strong>Reference Weight</strong></td>
<td>n.a.</td>
<td>between 5 % and 100 % of the balance’s operating range</td>
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