
	GILES CHEMICAL ~ PREMIER MAGNESIA		
	Company Procedure		
	Title: USP Analytical Balance Uncertainty Measurement	Number: L12-PR-100-013	
	Owner: Stephen Ballew	Revision: 1	
	Effective Date: 03/31/13	Page: 1 of 2	

## 1.0 Purpose

1. USP Section 41 states that “when substances are to be ‘accurately weighed’ for Assay the weighing is to be performed with a weighing device whose measurement uncertainty (random plus systematic error) does not exceed 0.1% of the reading.” The formula for arriving at this measurement uncertainty value is three times the standard deviation, of at least ten replicate measurements, divided by the amount weighed. The resulting value shall not exceed 0.001.
2. An uncertainty measurement will be performed on the analytical balance by a quality analyst on a monthly basis.

## 2.0 Scope

This procedure applies to the USP analytical balance. An uncertainty measurement will be performed on the analytical balance by QA Lab personnel on a weekly basis.

## 3.0 Responsibility

QA Lab personnel are responsible for performing this procedure.

## 4.0 Safety Considerations

Safety is a condition of employment. Employees are not authorized to work in an unsafe manner and are prohibited from harming the environment of the facility or community.

## 5.0 Materials/Equipment



- Forceps
- Calibration Weights

## 6.0 Procedure

1. Clean balance of any dust or powder using the brush supplied with the check weights, which are located in the marked box in the drawer below the analytical balance. After cleaning close all balance doors.
2. Press zero key and check that digital readout reads 0.00000 g within 4 seconds. Repeat once if digital readout fails to display 0.00000 g within 4 seconds.

### Controlled Document

Only those quality documents viewed through the Giles Chemical electronic Documentation System are officially controlled. All other copies, whether viewed through another computer program or a printed version, are not controlled and, therefore, the Quality Unit at Giles assumes no responsibility for accuracy of the document

	<b>GILES CHEMICAL ~ PREMIER MAGNESIA</b>		
	<b>Company Procedure</b>		
	Title: <b>USP Analytical Balance Uncertainty Measurement</b>	Number: <b>L12-PR-100-013</b>	
	Owner: <b>Stephen Ballew</b>	Revision: <b>1</b>	
	Effective Date: <b>03/31/13</b>	Page: <b>2 of 2</b>	

3. Press Adjust.int function key. The balance will run through a calibration, zeroing check and temperature adjusting procedure. When it is finished it will signal 'Adjustment Done' on the screen along with the temperature. If 'Adjustment Done' does not appear within one minute, repeat the procedure once. If 'Adjustment Done' still does not appear report the problem to the laboratory supervisor or the person responsible for the balance and contact METTLER TOLEDO's service organization for advice.
4. Measure the uncertainty of the balance by carefully weighing the 5 g check weight 10 times. Always use the forceps provided to handle the calibration weights. Do NOT handle weights with fingers. Record the results on the *USP Analytical Balance Uncertainty Measurement Log (L12-PR-100-F013)*

#### Calculating Uncertainty:

$$\frac{(3 * \text{Std. Dev. of ten measurements})}{\text{Amount Weighed}} \leq 0.001$$

The data can then be entered into an excel spreadsheet. This can be used to calculate standard deviation and uncertainty. Record these results on the *USP Analytical Balance Uncertainty Measurement Log (L12-PR-100-F013)*

#### Evaluation:

If the uncertainty is above the maximum amount of 0.001 then repeat the test. If the uncertainty maximum is exceeded again, level the balance, perform adjustment with built-in or external adjustment weights and repeat the test. If the control limit is still exceeded, report the problem to the laboratory supervisor or the person responsible for the balance, mark the balance as "out of uncertainty limits" and contact METTLER TOLEDO's service organization for advice.

#### 7.0 Reference Documents

*USP Analytical Balance Uncertainty Measurement Log (L12-PR-100-F013)*

#### 8.0 Change Information

Updated using *SOP Template Instructions (Q12-PR-100-004)* and *Document Numbering (Q12-PR-100-003)*

#### Controlled Document

Only those quality documents viewed through the Giles Chemical electronic Documentation System are officially controlled. All other copies, whether viewed through another computer program or a printed version, are not controlled and, therefore, the Quality Unit at Giles assumes no responsibility for accuracy of the document