

Mettler-Toledo GmbH
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Certificate USP General Chapter 41 "Balances"

Customer

Company: Omega Pharma Manufacturing
Address: 1900 Polaris Pkwy
City: Columbus **Contact:** John Doe
Zip/Postal: 43235 **Order Number:** PO12345
State/Province: OH

Weighing Device

Manufacturer: Mettler Toledo **Instrument Type:** Weighing Instrument
Model: XPR205DR **Asset Number:** 1111111111
Serial No.: 1234567890 **Terminal Model:** N/A
Building: GD **Terminal Serial No.:** N/A
Floor: 4th floor **Terminal Asset No.:** N/A
Room: GD610 **Alternate Asset No.:** EP98493211

Range	Max. Capacity	Readability (d)
1	81 g	0.00001 g
2	220 g	0.0001 g

Procedure

Reference Document: USP General Chapter 41
METTLER TOLEDO Work Instruction: Pharmacopeial Certificate WI 10000027820

This certificate contains measurements for the As Found and As Left tests.

The sensitivity of the weighing instrument was adjusted before the As Left tests.

As Found Test Date: 28-FEB-2021 **Service Technician:** 
As Left Test Date: 28-FEB-2021 Klaus Fritsch
Issue Date: 28-FEB-2021
Next Test Date: 28-FEB-2022

Summary of Results

Repeatability			As Found	As Left
Test	Smallest Net Weight	Tare Load	Assessment	Assessment
RP_SNW_0.05g	0.05 g	N/A	✓	✓
Accuracy			As Found	As Left
Sensitivity			✓	✓

Measurement Results

Repeatability

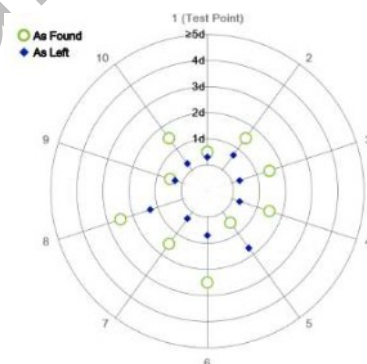
Repeatability Test RP_SNW_0.05g

Smallest Net Weight: 0.05 g
 Test Load: 10 g
 Tare Load: N/A

Tare Vessel ID: N/A
 Tare Vessel Description: N/A

	As Found	As Left
1	10.00002 g	10.00000 g
2	10.00003 g	10.00001 g
3	10.00001 g	9.99998 g
4	10.00001 g	10.00000 g
5	9.99999 g	10.00000 g
6	10.00001 g	10.00001 g
7	10.00001 g	10.00000 g
8	10.00001 g	9.99999 g
9	10.00002 g	9.99999 g
10	9.99999 g	10.00001 g

Mean Value	10.000010 g	9.999999 g
Standard Deviation	0.000012 g	0.000010 g
Calculation ¹⁾	0.0499 %	0.0398 %
Assessment ²⁾	0.05 % ✓	0.04 % ✓
Requirement	0.10 %	0.10 %
Minimum Weight ³⁾	0.02494 g	0.01989 g



The "d" in the graph represents the readability of the range/interval in which the test was performed. The results of this graph are based upon the absolute values of the differences from the mean value.

¹⁾ The following value is calculated: $2 * \text{standard deviation} / \text{smallest net weight}$. If the standard deviation s is smaller than the rounding error of $0.41 * d$ where d is the readability of the range/interval in which the test was performed, then s is replaced by $0.41 * d$.

²⁾ The assessment is carried out after the calculated value is mathematically rounded to the readability of the requirement of 0.10 %.

³⁾ Minimum weight = $2000 * s$. If the calculated standard deviation s is smaller than the rounding error of $0.41 * d$ where d is the readability of the range/interval in which the test was performed, then s is replaced by $0.41 * d$. In this case, minimum weight = $2000 * 0.41 * d$.

All intermediate calculations are performed in the software to 16 decimal places.

Accuracy

Sensitivity

	As Found	As Left
Test Load	200 g	200 g
CMV	200.0001 g	200.0001 g
Indication	199.9996 g	200.0002 g
Deviation ¹⁾	- 0.0005 g ✓	0.0001 g ✓
Requirement	0.1000 g	0.1000 g

¹⁾ The sensitivity test is passed if the absolute value of the deviation $\leq 0.05\%$ of the test load value. The requirement for the assessment of sensitivity is 0.05% . This ensures adherence to the overall accuracy requirement of 0.10% because other balance properties might also limit the accuracy of the instrument.

Reference Weights

All weights used for metrological testing are traceable to national or international standards. The weights were calibrated and certified by an accredited calibration laboratory.

Weight Set 1: OIML E₂

Weight Set No.:	WS12345_E2	Date of Issue:	04-JAN-2021
Certificate Number:	34567890	Calibration Due Date:	03-JAN-2023

Remarks

N/A

Sample Document