

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

Customer

Company:	Omega Pharma Manufacturing	Contact:	John Doe
Address:	1900 Polaris Pkwy	Order Number:	PO12345
City:	Columbus		
Zip/Postal:	43235		
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:	4 th 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

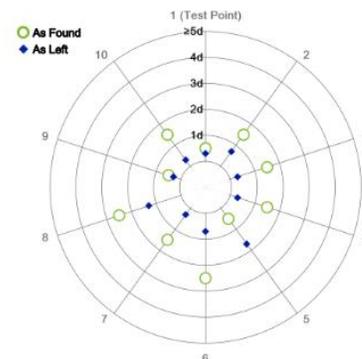
Repeatability Test RP_SNW_0.05g

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
Assessment ¹⁾	0.05 % ✓	0.04 % ✓
Requirement	0.10 %	0.10 %
Minimum Weight ²⁾	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 repeatability test is passed if $2 * \text{standard deviation} / \text{smallest net weight} \leq 0.10 \%$. If the calculated standard deviation results in a value 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 the standard deviation is replaced by $0.41 * d$ for the assessment.

²⁾ Minimum weight = $2000 * \text{standard deviation}$. If the calculated standard deviation results in a value 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 the standard deviation is replaced by $0.41 * d$. In this case, minimum weight = $2000 * 0.41 * d$.

All calculations are performed in the software to 16 decimal places, however the printed results are rounded according the following rules: The standard deviation is rounded mathematically to one digit further than the readability of the range/interval in which the test was performed. The minimum weight is rounded mathematically to three significant figures. For the repeatability assessment, the printed result of the formula ($2 * \text{standard deviation} / \text{smallest net weight}$) or ($2 * 0.41 * d / \text{smallest net weight}$, respectively) is rounded mathematically to the same readability as the repeatability requirement (0.10%), i.e. with two digits after the decimal when presented as a percentage.

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.:	<u>WS12345_E2</u>	Date of Issue:	<u>04-JAN-2021</u>
Certificate Number:	<u>34567890</u>	Calibration Due Date:	<u>03-JAN-2023</u>

Remarks

N/A