**Certificate ID**
CH0001-057-210228-EP

**Mettler-Toledo GmbH**
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METTLER TOLEDO

# Certificate Ph. Eur. General Chapter 2.1.7 "Balances for Analytical Purposes"

## 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:** | Ph. Eur. General Chapter 2.1.7 |
| **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-2011 | **Service Technician:** | Klaus Fritsch |
| **As Left Test Date:** | 28-FEB-2021 | | |
| **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

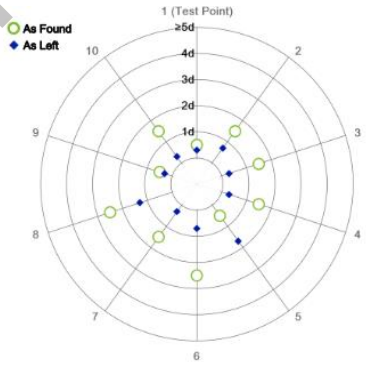
### Repeatability Test RP_SNW_0.05g

**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 * standard deviation / smallest net weight ≤ 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 * 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*standard deviation / smallest net weight) or (2 * 0.41*d / 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 ≤ 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 $E_2$**

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

# Remarks

N/A