

Mettler-Toledo GmbH
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Certificate Ph. Eur. General Chapter 2.1.7 "Balances for Analytical Purposes"

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: | 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: |  |
| 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 | N/A | N/A |
| RP_SNW_0.05g | 0.05 g | N/A | ✓ | ✓ |
| Accuracy | | | As Found | As Left |
| Eccentricity | | | ✓ | ✓ |
| Linearity | | | ✓ | ✓ |
| Sensitivity | | | ✓ | ✓ |

Measurement Results

Repeatability

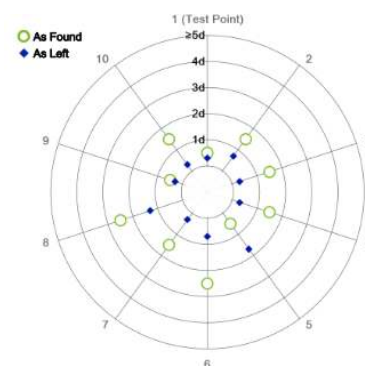
Repeatability Test RP_SNW_0.05g

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 $2 \cdot \text{standard deviation} / \text{smallest net weight} \leq 0.10 \%$. If the calculated standard deviation results in a value smaller than the rounding error of $0.41 \cdot d$ where d is the readability of the range/interval in which the test was performed, then the standard deviation is replaced by $0.41 \cdot d$ for the assessment.

²⁾ Minimum weight = $2000 \cdot \text{standard deviation}$. If the calculated standard deviation results in a value smaller than the rounding error of $0.41 \cdot d$ where d is the readability of the range/interval in which the test was performed, then the standard deviation is replaced by $0.41 \cdot d$. In this case, minimum weight = $2000 \cdot 0.41 \cdot d$.

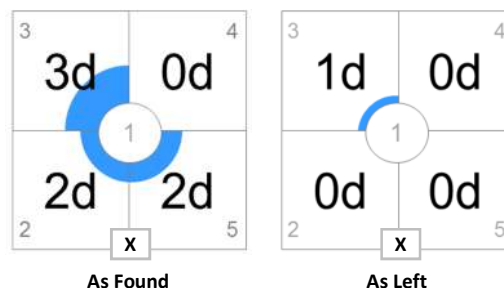
All calculations are performed in the software to 16 decimal places, however the printed results are rounded according the following rules: The standard deviation is rounded mathematically to one digit further than the readability of the range/interval in which the test was performed. The minimum weight is rounded mathematically to three significant figures. For the repeatability assessment, the printed result of the formula ($2 \cdot \text{standard deviation} / \text{smallest net weight}$) or ($2 \cdot 0.41 \cdot d / \text{smallest net weight}$, 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

Eccentricity

Test Load: 70 g

| Position | As Found | As Left |
|------------------------------------|--------------------|--------------------|
| 1 | 70.00000 g | 70.00000 g |
| 2 | 70.00002 g | 70.00000 g |
| 3 | 69.99997 g | 70.00001 g |
| 4 | 70.00000 g | 70.00000 g |
| 5 | 70.00002 g | 70.00000 g |
| Max Deviation ¹⁾ | 0.00003 g ✓ | 0.00001 g ✓ |
| Requirement | 0.03500 g | 0.03500 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 values of the differences from the center value.

¹⁾ The eccentricity test is passed if the maximum deviation $\leq 0.05\%$ of the test load value. The requirement for the assessment of an individual balance property in respect to accuracy 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.

Linearity

As Found

| | Test Load | CMV | Indication | Deviation ¹⁾ | Requirement |
|---|-----------|------------|------------|-------------------------|-------------|
| 1 | 50 g | 50.00002 g | 50.00005 g | 0.00003 g ✓ | 0.02500 g |
| 2 | 100 g | 99.9999 g | 100.0000 g | 0.0001 g ✓ | 0.05000 g |
| 3 | 150 g | 150.0001 g | 150.0003 g | 0.0002 g ✓ | 0.07500 g |
| 4 | 220 g | 220.0001 g | 200.0007 g | 0.0006 g ✓ | 0.11000 g |

As Left

| | Test Load | CMV | Indication | Deviation ¹⁾ | Requirement |
|---|-----------|------------|------------|-------------------------|-------------|
| 1 | 50 g | 50.00002 g | 50.00003 g | 0.00001 g ✓ | 0.02500 g |
| 2 | 100 g | 99.9999 g | 99.9999 g | 0.0000 g ✓ | 0.05000 g |
| 3 | 150 g | 150.0001 g | 150.0001 g | 0.0000 g ✓ | 0.07500 g |
| 4 | 220 g | 220.0001 g | 220.0002 g | 0.0001 g ✓ | 0.11000 g |

¹⁾ The linearity test is passed if the maximum deviation $\leq 0.05\%$ of the test load value. The requirement for the assessment of an individual balance property in respect to accuracy 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.

Sensitivity

The largest test point of the linearity test is also used to assess sensitivity.

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

Remark regarding this mockup: Within the Accuracy test, only the test of sensitivity is compulsory. Tests of eccentricity and linearity are voluntary and can be added upon the user's request.