

Balance and Pipette Verification Record

Meridian Analytical Services — Metrology & Instrument QC

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Department	Quality Control — Metrology	Location	QC Lab, Building 2, Room 214
Prepared By	Farida Chowdhury, Metrology Technician	Approved By	Rezaul Karim, QA Manager
Record Type	Gravimetric Verification (Balance + Pipettes)	Retention	7 years from effective date

This record documents the routine gravimetric verification of one analytical balance and four air-displacement pipettes used within the Meridian QC Lab. It captures raw readings, computed accuracy and precision against ISO 8655 and OIML R76 tolerance limits, resulting correction factors, and the next-due date for each instrument. This record is controlled; superseded copies must be marked *OBSOLETE* and retained per the site document-control procedure.

1 Purpose and Scope

1.1 Purpose

This record establishes objective evidence that the analytical balance and pipettes listed in Section 2 perform within their manufacturer- and standard-defined tolerance limits before release for use in formulation weighing, titration, and volumetric dispensing tasks. Verification is performed gravimetrically: mass readings of a certified reference weight (balance) or of dispensed water (pipettes) are converted to volume and compared against tolerance limits defined in ISO 8655 [4, 5] and OIML R76-1 [1], with balance performance additionally cross-checked against ASTM E898 [2] and ASTM E177 [3].

1.2 Scope

This record applies to:

- One semi-micro analytical balance (Section 4), verified for linearity, repeatability, and corner-load (eccentricity) error.
- Four single-channel air-displacement pipettes (Section 5), each verified gravimetrically at three test volumes per ISO 8655-6 Method A.

It does *not* cover multichannel pipettes, bulk dispensers, or the balance’s initial factory calibration certificate, which is held separately in the metrology asset file.

1.3 Responsibilities

- **Metrology Technician** — performs the gravimetric verification, records raw readings, computes accuracy, precision, and correction factors, and tags any out-of-tolerance instrument for quarantine.
- **QA Manager** — reviews computed results against tolerance limits, dispositions nonconformances, and approves the record for release.
- **Lab Manager** — schedules the next verification interval and ensures out-of-service instruments are withheld from use until requalified.

1.4 Reference Standards

Gravimetric method, environmental correction, and tolerance limits are drawn from [4], [5], [1], [2], [3], and USP General Chapter <41> on weighing devices [6].

Asset ID	Instrument	Model	Serial No.	Range
EQ-BAL-014	Analytical balance	Meridian MSA204S	MSA204S-08871	0.1 mg – 220 g
EQ-PIP-101	Air-disp. pipette	Nexa Precision P10	NX10-33920	1 – 10 µL
EQ-PIP-102	Air-disp. pipette	Nexa Precision P200	NX200-11284	20 – 200 µL
EQ-PIP-103	Air-disp. pipette	Nexa Precision P1000	NX1K-55017	100 – 1000 µL
EQ-PIP-104	Air-disp. pipette	Nexa Precision P5000	NX5K-90231	1000 – 5000 µL

2 Equipment and Environmental Conditions

2.1 Instruments Under Test

Reference mass standards: OIML Class E2 weight set, Certificate No. NW-2026-0451, traceable to the national metrology institute, issued 12 Jan 2026, next recertification due 12 Jan 2028. Reference liquid: freshly drawn Type I reagent water, equilibrated to ambient lab temperature for > 2 hours before use.

2.2 Environmental Conditions at Time of Verification

Parameter	Specified Range	Recorded Value	In Range?
Ambient temperature	20 °C – 24 °C	21.8 °C	✔ PASS
Relative humidity	40% – 60% RH	47% RH	✔ PASS
Barometric pressure	990 – 1030 hPa	1008 hPa	✔ PASS
Draft / vibration shield	Enclosed, doors closed	Confirmed enclosed	✔ PASS
Bench level (bubble)	Centred	Centred, adjusted N/A	✔ PASS

All readings below were taken with the balance draft shield closed and the bench isolated from foot-traffic vibration. Water density at 21.8 °C was taken as 0.99805 g/mL for gravimetric volume conversion (Section 5.1).

3 Balance Verification (EQ-BAL-014)

3.1 Method

Verification followed the gravimetric linearity, repeatability, and eccentricity checks described in OIML R76-1 [1] and ASTM E898 [2], using Class E2 reference weights handled with forceps and allowed to thermally equilibrate on the balance table for 10 minutes before each series.

3.2 Linearity (Multi-Point Load Check)

Nominal Load	Ref. Wt. ID	Certified Mass (g)	Displayed (g)	Deviation (mg)	Tolerance	Result
Tare (0 g)	—	0.0000	0.0000	0.00	±0.10 mg	✔ PASS
1 g	E2-011	1.0000	1.0001	+0.10	±0.20 mg	✔ PASS
10 g	E2-014	10.0000	9.9999	–0.10	±0.30 mg	✔ PASS
50 g	E2-019	50.0001	50.0004	+0.30	±0.50 mg	✔ PASS
100 g	E2-023	100.0002	99.9996	–0.60	±0.80 mg	✔ PASS
200 g	E2-031	200.0003	200.0011	+0.80	±1.00 mg	✔ PASS

3.3 Repeatability (10 Replicates at 100 g Nominal Load)

R1	R2	R3	R4	R5	R6	R7	R8	R9	R10
100.0004	100.0003	100.0005	100.0004	100.0002	100.0005	100.0003	100.0004	100.0006	100.0003

All values in grams (g).

Mean reading	100.00039 g
Standard deviation (s)	0.00012 g
Coefficient of variation (%CV)	0.00012%
Repeatability limit	≤0.010%
Result	✓ PASS

3.4 Eccentricity (Corner-Load) Check — 50 g Reference Weight

Position	Displayed (g)	Deviation vs. Centre (mg)	Tolerance	Result
Centre	50.0001	—	—	—
Front-Left	50.0009	+0.80	±1.5 mg	✓ PASS
Front-Right	49.9995	-0.60	±1.5 mg	✓ PASS
Back-Left	50.0003	+0.20	±1.5 mg	✓ PASS
Back-Right	50.0011	+1.00	±1.5 mg	✓ PASS

Overall balance verification result: ✓ PASS. All linearity, repeatability, and eccentricity checks are within OIML R76-1 Class I acceptance limits for a 0.1 mg readability balance. No adjustment or correction factor is required; the balance's internal calibration remains valid for the interval defined in Section 7.

4 Pipette Verification

4.1 Method

Each pipette was tested gravimetrically per ISO 8655-6 Method A [5], dispensing reagent water onto the balance pan at three test volumes (100%, 50%, and 10% of nominal capacity), $n = 10$ replicates per volume. Dispensed mass was converted to volume using the Z-factor for water at the recorded ambient temperature and pressure (Section 2.2):

$$V = W \times Z(T, p), \quad Z(21.8\text{ }^{\circ}\text{C}, 1008\text{ hPa}) = 1.0032\text{ L/mg} \quad (1)$$

Accuracy (systematic error) is the percentage deviation of the mean measured volume from the target volume; precision (random error) is the percentage coefficient of variation across the 10 replicates. The correction factor $CF = V_{\text{target}}/V_{\text{mean}}$ is recorded for reference but is *not* applied to the pipette dial — Nexa Precision pipettes are piston-stroke calibrated at the manufacturer and are replaced or serviced, not field-adjusted, when out of tolerance.

4.2 EQ-PIP-101 — Nexa Precision P10 (1–10 µL)

Test Vol.	n	Mean Vol. (µL)	Accuracy	Acc. Limit	Precision	Prec. Limit	CF	Result
10 µL(100%)	10	9.997	-0.03%	±2.5%	0.21%	≤1.2%	1.0003	✓ PASS
5 µL(50%)	10	5.002	+0.04%	±3.0%	0.28%	≤1.5%	0.9996	✓ PASS
1 µL(10%)	10	1.000	+0.02%	±8.0%	0.90%	≤4.0%	1.0000	✓ PASS

4.3 EQ-PIP-102 — Nexa Precision P200 (20–200 µL)

Test Vol.	n	Mean Vol. (µL)	Accuracy	Acc. Limit	Precision	Prec. Limit	CF	Result
200 µL(100%)	10	199.91	-0.05%	±0.8%	0.18%	≤0.3%	1.0005	✓ PASS
100 µL(50%)	10	100.07	+0.07%	±1.0%	0.22%	≤0.4%	0.9993	✓ PASS
20 µL(10%)	10	19.94	-0.30%	±3.0%	0.55%	≤1.2%	1.0030	✓ PASS

4.4 EQ-PIP-103 — Nexa Precision P1000 (100–1000 µL)

Test Vol.	n	Mean Vol. (µL)	Accuracy	Acc. Limit	Precision	Prec. Limit	CF	Result
1000 µL(100%)	10	999.2	-0.08%	±0.6%	0.12%	≤0.2%	1.0008	✓ PASS
500 µL(50%)	10	500.6	+0.12%	±0.8%	0.18%	≤0.3%	0.9988	✓ PASS
100 µL(10%)	10	99.5	-0.50%	±1.5%	0.40%	≤0.6%	1.0050	✓ PASS

Test Vol.	<i>n</i>	Mean Vol. (μL)	Accuracy	Acc. Limit	Precision	Prec. Limit	CF	Result
5000 μL(100%)	10	4989.6	−0.21%	±0.6%	0.15%	≤0.2%	1.0021	✓ PASS
2500 μL(50%)	10	2504.1	+0.16%	±0.8%	0.20%	≤0.3%	0.9984	✓ PASS
1000 μL(10%)	10	1012.5	+1.25%	±1.5%	0.62%	≤0.50%	N/A	✗ FAIL

4.5 EQ-PIP-104 — Nexa Precision P5000 (1000–5000 μL)

⚠ Nonconformance — EQ-PIP-104

Precision at the 10% test volume (0.62% CV) exceeds the ISO 8655 limit of 0.50%, while accuracy remains within limit. The pipette is tagged **OUT OF SERVICE** pending piston seal inspection under NCR-2026-0113 (Section 6.2). Its two passing test volumes do not offset the failing result — the overall pipette disposition is ✗ **FAIL** per the “worst result governs” rule in Section 6.1.

5 Tolerance Criteria and Nonconformance Handling

5.1 Acceptance Rule

An instrument passes overall verification only if every tested load or volume, at every tested point, meets both its accuracy and precision limit. A single out-of-tolerance result fails the whole instrument for that verification cycle — partial pass is not a valid disposition, consistent with the pipette policy applied in Section 5.5.

5.2 ISO 8655 Tolerance Summary by Volume Range (Air-Displacement Pipettes)

Nominal Volume Range	Accuracy Limit	Precision Limit (CV)
≥1000 μL	±0.6%	≤0.20%
100 μL– 999 μL	±0.8% – ±1.5%	≤0.30% – ≤0.60%
10 μL– 99 μL	±1.0% – ±3.0%	≤0.40% – ≤1.2%
<10 μL	±2.5% – ±8.0%	≤1.2% – ≤4.0%

Tighter limits apply at 100% of a pipette’s nominal capacity; limits widen at lower test volumes (50%, 10%) as relative error grows for the same absolute dispensing variance. Balance tolerances follow OIML R76-1 Class I bands applied per Section 4, scaled to load as shown in Section 4.2.

5.3 Corrective Action Procedure

When a result exceeds its tolerance limit, the technician:

- Repeats the failing test point once, immediately, to rule out a transient handling error (draft, static charge, air bubble in the tip).
- If the repeat still fails, applies an **OUT OF SERVICE** tag to the instrument and physically removes it from the bench.
- Opens a nonconformance record (NCR) referencing this document number and the specific test point that failed.
- Notifies the QA Manager and any staff who used the instrument since its last passing verification, so downstream results can be risk-assessed.
- Routes the instrument to service (in-house piston/seal inspection or manufacturer repair) and re-verifies fully — all three test volumes, not only the one that failed — before returning it to use.

5.4 Open Nonconformance — NCR-2026-0113

Instrument	EQ-PIP-104, Nexa Precision P5000
Failed point	1000 μL(10% of nominal), precision 0.62% vs. ≤0.50% limit
Repeat result	0.59% CV — still out of tolerance, tag applied
Disposition	Out of service; piston seal inspection requested from vendor service desk
Impact review	Formulation batches Nexa-2216 and Nexa-2219 used this pipette in the affected volume band; QA impact assessment opened separately
Status at issue of this record	Open — awaiting service appointment

6 Verification Schedule and Authorization

Asset ID	Instrument	Interval	Next Due	Status
EQ-BAL-014	Meridian MSA204S balance	12 months	04 Aug 2027	✓ PASS
EQ-PIP-101	Nexa Precision P10	6 months	04 Feb 2027	✓ PASS
EQ-PIP-102	Nexa Precision P200	6 months	04 Feb 2027	✓ PASS
EQ-PIP-103	Nexa Precision P1000	6 months	04 Feb 2027	✓ PASS
EQ-PIP-104	Nexa Precision P5000	—	<i>withheld until requalified</i>	⚠ OUT OF SERVICE

6.1 Next-Due Summary



EQ-PIP-104 is excluded from the routine 6-month cycle above until NCR-2026-0113 (Section 6.4) closes with a passing full re-verification; its next-due date will be set to 6 months from that requalification date, not from this record's issue date.

6.2 Sign-Off

Verified By (Metrology Technician) Farida Chowdhury _____	Date _____
Reviewed By (QA Manager) Rezaul Karim _____	Date _____
Approved By (Lab Manager) Imran Hasan Talukder _____	Date _____

This record is void if any signature block above is incomplete. Retain per Section 1 (document control) for 7 years from the effective date.

References

- [1] OIML R76-1:2006 non-automatic weighing instruments — part 1: Metrological and technical requirements. Technical report, International Organization of Legal Metrology, Paris, France, 2006.
- [2] ASTM E898-88(2019) standard test method of testing top-loading, direct-reading laboratory scales and balances. Technical report, ASTM International, West Conshohocken, PA, 2019.
- [3] ASTM E177-20 standard practice for use of the terms precision and bias in astm test methods. Technical report, ASTM International, West Conshohocken, PA, 2020.
- [4] ISO 8655-1:2022 piston-operated volumetric apparatus — part 1: Terminology, general requirements and user recommendations. Technical report, International Organization for Standardization, Geneva, Switzerland, 2022.
- [5] ISO 8655-6:2022 piston-operated volumetric apparatus — part 6: Gravimetric reference measurement procedure for the determination of volume. Technical report, International Organization for Standardization, Geneva, Switzerland, 2022.
- [6] USP General Chapter <41> balances. Technical report, United States Pharmacopeial Convention, Rockville, MD, 2023.