KOVERA LABS

# CERTIFICATE OF ANALYSIS

REPORT # KVR-2026-DEC9C3

**Client(s):** One Aminos **Certified:** 10/24/2026

This Certificate of Analysis certifies that the sample listed herein was tested by Kovera Labs using validated analytical methods and was found to meet the stated specifications at the time of analysis.

## SAMPLE INFORMATION

| | | | |
|---|---|---|---|
| **Product** | Selank | **Form** | Lyophilized Powder |
| **Batch** | ONE-SEL-102226 | **Labeled Qty** | 10 mg |
| **Cap Color** | Black | **Crimp Color** | Silver |

## TEST RESULTS

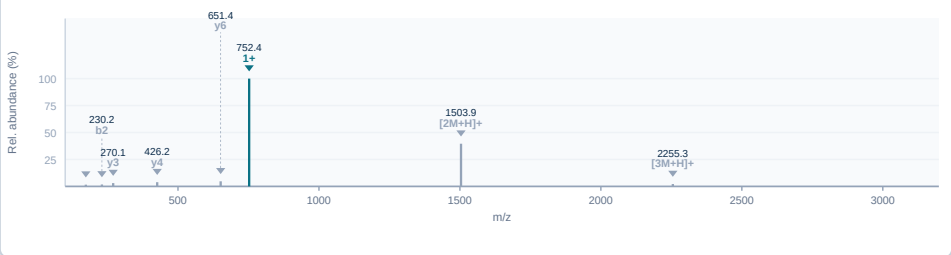
| | REFERENCE STANDARD | RESULT |
|---|---|---|
| **Batch Avg Purity** | (>98%) | 99.563% ✓ |
| **Batch Avg Net Content** | (~10mg) | 9.44 mg ✓ |
| **Identity Confirmation (LC-MS)** | (Selank) | Selank ✓ |
| **Endotoxin Safety Screen** | (≤0.5 EU/mL) | PASS ✓ |
| **Fentanyl Presence Analysis** | (Not Detected) | Not Detected ✓ |
| **Rapid Sterility Screening** | (No Growth) | No Growth ✓ |
| **Heavy Metal Screening** | (Negative) | Negative ✓ |

## BATCH CONFORMITY RESULTS

| Vial | Purity (%) | Net Content (mg) |
|---|---|---|
| Vial 1 | 99.469 | 9.48 |
| Vial 2 | 99.657 | 9.39 |
| **Batch Average** | **99.563%** | **9.44 mg** |

## MASS SPECTRUM

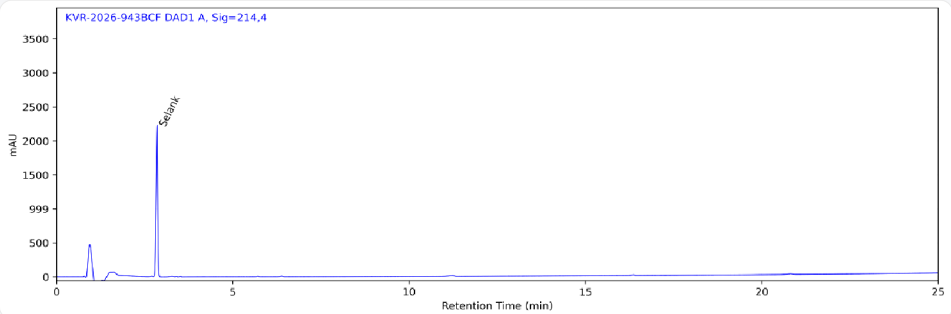
ESI + mode, MS1 centroid  Charge states confirmed **1**




*Each coloured stick is a confirmed charge state of the compound(s) above, drawn at the intensity measured for that ion. Height is relative to the strongest confirmed ion and is not proportional to concentration; content is reported in the Test Results above. The 7 grey stick(s) are the same compound's own in-source fragment and multimer ions, labelled by species: they are produced from the analyte in the ion source and are not separate substances in the vial.*

## CHROMATOGRAM

*Method: RP-HPLC | Column: C18 | Detection: DAD @ 214 nm*




Lemar Arghandiwal
Lab Director

koveralabs.com/verify

Report#: KVR-2026-DEC9C3
Access Code: 080FJKX

KOVERA LABS

# BACTERIAL ENDOTOXIN ANALYSIS

(Kinetic Chromogenic LAL, USP <85>)

Report Number: **KVR-2026-DEC9C3**

## CLIENT & SAMPLE INFORMATION

| | | | |
|---|---|---|---|
| **Client** | One Aminos | **Certified Date** | 10/24/2026 |
| **Product Name** | Selank | **Strength** | 10 mg |
| **Lot / Batch** | ONE-SEL-102226 | **Condition** | Lyophilized |

This Certificate of Analysis certifies that the sample listed herein was tested for bacterial endotoxin using a kinetic chromogenic LAL assay in accordance with USP <85> Bacterial Endotoxins Test.

## TEST METHODOLOGY

| | | | |
|---|---|---|---|
| **Test Performed** | Quantitative Bacterial Endotoxin Test | **Compendial Ref** | USP <85> |
| **Assay Type** | Kinetic Turbidimetric | **Detection λ** | 660 nm |
| **Detection Range** | 0.01 - 1.0 EU/mL | **Endotoxin Std** | E. coli O111:B4 |
| **Dilution Vol** | 2.0 mL | **Matrix** | LAL Reagent Water |

## QUANTITATIVE RESULTS

| Parameter | Result |
|---|---|
| Endotoxin Level | < 0.05 EU/mL |
| Acceptance Limit | ≤ 0.5 EU/mL |
| Sample CV (%) | 4.2% |
| Spike CV (%) | 2.9% |
| Spike Recovery (%) | 91% |
| **Final Determination** | **PASS** |

## CONTROLS

| Control | Expected | Observed | Status |
|---|---|---|---|
| Positive Control | Detectable | As expected | Pass |
| Negative Control | No signal | As expected | Pass |

## INTERPRETATION

Endotoxin content was quantitatively determined using a kinetic chromogenic LAL assay in accordance with USP <85>. Result reported as below quantitation threshold. The measured endotoxin level meets the specified acceptance criteria. The sample passes the endotoxin limit test.

## AUTHORIZATION

REVIEWED BY

**Lemar Arghandiwal**

Lab Director

## CLIENT & SAMPLE INFORMATION

| | | | |
|---|---|---|---|
| **Client** | One Aminos | **Certified Date** | October 24, 2026 |
| **Product Name** | Selank | **Strength** | 10 mg |
| **Lot / Batch** | ONE-SEL-102226 | **Condition** | Lyophilized |

ICP-MS metals analysis performed using EPA-referenced methods; results evaluated against internal acceptance criteria.

## TEST METHODOLOGY

| | | | |
|---|---|---|---|
| **Test Performed** | Elemental Impurities Analysis | **Instrument** | ICP-MS |
| **Sample Prep** | $HNO_3$ / $H_2O_2$ matrix | **Calibration** | Multi-element standard curve |
| **Internal Std** | Sc, Ge, In, Bi | **Material Type** | Raw Material (Research Use) |

## ELEMENTAL IMPURITIES RESULTS

| Element | Result (ppm) | Acceptance Limit (ppm) | Status |
|---|---|---|---|
| Pb Lead | < 0.5 | ≤ 10 | PASS |
| As Arsenic | < 0.15 | ≤ 1.5 | PASS |
| Cd Cadmium | < 0.05 | ≤ 0.5 | PASS |
| Hg Mercury | < 0.3 | ≤ 3 | PASS |

## METHOD SUITABILITY (SPIKE RECOVERY)

| Element | Spike Level | Recovery | Criteria |
|---|---|---|---|
| Pb Lead | 5 ppm | 98% | 70–150% |
| As Arsenic | 0.75 ppm | 102% | 70–150% |
| Cd Cadmium | 0.25 ppm | 95% | 70–150% |
| Hg Mercury | 1.5 ppm | 91% | 70–150% |

Spike recovery confirms method suitability for the sample matrix.

## INTERPRETATION

Elemental impurities were determined using ICP-MS with EPA-referenced analytical methods. All tested elements (Pb, As, Cd, Hg) are below the stated acceptance limits. Spike recovery values fall within acceptable ranges, confirming method suitability. The sample meets the stated acceptance criteria for elemental impurities.

## QUALITY CONTROL

**Method Blank:** Pass **CCV:** Pass **Duplicate RPD:** < 20%

## AUTHORIZATION

REVIEWED BY
**Lemar Arghandiwal**
Lab Director

KOVERA LABS

# RAPID STERILITY SCREEN

Report Number: **KVR-2026-DEC9C3**

## CLIENT & SAMPLE INFORMATION

| | | | |
|---|---|---|---|
| **Client** | One Aminos | **Sample Name** | Selank |
| **Lot Number** | ONE-SEL-102226 | **Sample Matrix** | Lyophilized Powder |
| **Date Received** | 10/23/2026 | **Certified Date** | 10/25/2026 |

## TEST METHODOLOGY

### RAPID STERILITY SCREENING METHOD

Sample is reconstituted and incubated in growth media under controlled conditions. Cultures are monitored for microbial growth over the incubation period. This rapid screening method provides preliminary sterility assessment and is suitable for quality control purposes. For regulatory compliance, full compendial sterility testing may be required.

## TEST RESULTS

| TEST PARAMETER | SPECIFICATION | RESULT | STATUS |
|---|---|---|---|
| Bacteria (Aerobic/Anaerobic) | No Growth | **No Growth** | PASS |
| Fungi / Yeast | Not Detected | **Not Detected** | PASS |

| TEST METHOD | INCUBATION PERIOD | TEMPERATURE |
|---|---|---|
| **Rapid Sterility** | **2 days** | **30-35C** |

## FINAL DETERMINATION

STERILITY SCREEN RESULT

**SAMPLE PASSES STERILITY SCREEN**

No microbial growth detected during incubation period