NORTHCHAIN
ANALYTICS

# CERTIFICATE OF ANALYSIS

**REPORT #:** SB-2026-80859 | **PASS**

| | | | |
|---|---|---|---|
| **Client** | SynovaBiotech | **Analysis date** | 9/13/26 |
| **Report #** | SB-2026-80859 | **Certified date** | 9/13/26 |

## SAMPLE INFORMATION

| | | | |
|---|---|---|---|
| **Product** | Semax | **Form** | Lyophilized Powder |
| **Lot / batch** | SM424 | **Labeled qty** | 10mg |
| **Cap color** | Transparent purple | **Crimp color** | Silver |

## TEST RESULTS

| Analysis / method | Reference standard | Result | Review |
|---|---|---|---|
| **Purity (HPLC)** | >98% | 99.43% | PASS |
| **Net content** | 10mg | 10.12mg | PASS |
| **Identity (LC-MS)** | (Semax) | Semax | PASS |
| **Bacterial endotoxin** | <0.5EU/ml | PASS | PASS |
| **Microbial growth screen** | no growth | no microbial growth detected | PASS |

## HEAVY METAL SCREENING

| Analyte | Result | Status |
|---|---|---|
| **Arsenic (As)** | negative | PASS |
| **Cadmium (Cd)** | negative | PASS |
| **Lead (Pb)** | negative | PASS |
| **Mercury (Hg)** | negative | PASS |

## BATCH CONFORMITY RESULTS / ONE VIAL TESTED

| Sample | Purity (%) | Net content (mg) |
|---|---|---|
| **Vial 1** | 99.43 | 10.12 |

One submitted vial tested. These findings describe this vial; batch-wide variation was not measured.

## CHROMATOGRAPHIC RECORD / TRACEABILITY

| | | | |
|---|---|---|---|
| **Method** | RP-HPLC | **Run / data ID** | SK-20260918-002 |
| **Column** | C18 | **Detector / wavelength** | DAD at 214nm |

## AUTHORIZATION

| | | | |
|---|---|---|---|
| **Reviewed by** | Paul Molina | **Review date** | 9/13/26 |
| **Issued by** | Paul Molina | **Verification key** | SBPSM10 |



NORTHCHAIN
ANALYTICS

# BACTERIAL ENDOTOXIN ANALYSIS

**REPORT #:** SB-2026-80859 | **PASS**

ASSAY / METHOD AS PERFORMED

## CLIENT & SAMPLE INFORMATION

| | | | |
|---|---|---|---|
| **Client** | SynovaBiotech | **Report ID** | SB-2026-80859 |
| **Product name** | Semax | **Strength** | 10mg |
| **Lot / batch** | SM424 | **Condition** | Lyophilized Powder |
| **Report date** | 9/12/26 | **Access key** | SBPSM10 |

## TEST METHODOLOGY

| | | | |
|---|---|---|---|
| **Test performed** | Quantitative Bacterial Endotoxin Test | **Compendial reference** | USP<85> |
| **Assay type** | Kinetic Turbidimetric | **Detection wavelength** | 660nm |
| **Detection range** | 0.01-1.0EU/ml | **Endotoxin standard** | E.coli 0111:B4 |
| **Dilution volume** | 2.0ml | **Matrix** | LAL Reagent Water |

## QUANTITATIVE RESULTS

| Parameter | Result | Controls | Status |
|---|---|---|---|
| **Endotoxin level** | <0.07 EU/ml | Positive control | PASS |
| **Acceptance limit** | ≤0.5EU/ML | Negative control | PASS |
| **Sample CV (%)** | 2.80% | | |
| **Spike CV (%)** | 3.00% | | |
| **Spike recovery (%)** | 88% | | |
| **Final determination** | PASS | | |

## INTERPRETATION

Endotoxin content was quantitatively determined using a kinetic turbidimetric 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** | Paul Molina | **Review date** | 9/13/26 |
| **Issued by** | Paul Molina | **Method record ID** | 103652SM |



NORTHCHAIN
ANALYTICS

# HEAVY METALS ANALYSIS

REPORT #: SB-2026-80859 | PASS

ICP-MS / METHOD AS PERFORMED

## CLIENT & SAMPLE INFORMATION

| | | | |
|---|---|---|---|
| **Client** | SynovaBiotech | **Report ID** | SB-2026-80859 |
| **Product name** | Semax | **Strength** | 10mg |
| **Lot / batch** | SM424 | **Condition** | Lyophilized Powder |
| **Report date** | 9/12/26 | **Access key** | SBPSM10 |

## TEST METHODOLOGY

| | | | |
|---|---|---|---|
| **Test performed** | Elemental Impurities Analysis | **Instrument** | ICP-MS |
| **Sample preparation** | $HNO^3/H^20^2$ matrix | **Calibration** | Multi-element standard curve |
| **Internal standards** | Sc,Ge,In,Bi | **Material type** | Raw Material |

## ELEMENTAL IMPURITIES RESULTS

| Element | Result / unit | Acceptance limit | Status |
|---|---|---|---|
| **Lead (Pb)** | 0.5 ppm | ≤10 | PASS |
| **Arsenic (As)** | 0.15 ppm | ≤1.5 | PASS |
| **Cadmium (Cd)** | 0.05 ppm | ≤0.5 | PASS |
| **Mercury (Hg)** | 0.2 ppm | ≤3 | PASS |

## METHOD SUITABILITY / SPIKE RECOVERY

| Element | Spike level | Recovery (%) | Criteria |
|---|---|---|---|
| **Lead (Pb)** | 5 ppm | 98% | 70-150% |
| **Arsenic (As)** | 0.75 ppm | 102% | 70-150% |
| **Cadmium (Cd)** | 0.25 ppm | 95% | 70-150% |
| **Mercury (Hg)** | 0.25 ppm | 91% | 70-150% |

## QUALITY CONTROL & INTERPRETATION

| | | | |
|---|---|---|---|
| **Method blank** | PASS | **CCV / calibration** | PASS |
| **Duplicate RPD** | ≤20% | **Method run ID** | SM535 |

## AUTHORIZATION

| | | | |
|---|---|---|---|
| **Reviewed by** | Paul Molina | **Review date** | 9/13/26 |



NORTHCHAIN
ANALYTICS

# MICROBIAL GROWTH SCREENING

**REPORT #:** SB-2026-80859

INCUBATION METHOD AS PERFORMED

## CLIENT & SAMPLE INFORMATION

| | | | |
|---|---|---|---|
| **Client** | SynovaBiotech | **Report ID** | SB-2026-80859 |
| **Product name** | Semax | **Strength** | 10mg |
| **Lot / batch** | SM424 | **Condition** | Lyophilized Powder |
| **Report date** | 9/26/26 | **Access key** | SBPSM10 |

## TEST METHODOLOGY

| | | | |
|---|---|---|---|
| **Test performed** | 14 Day Microbial Growth Screening | **Culture system** | Aerobic and anaerobic bottles |
| **Incubation period** | 14 days | **Detection principle** | Colorimetric $CO_2$ detection |
| **Sample requirement** | 1 vial (destructive) | **Condition as received** | Sealed |

## TEST RESULTS

| Parameter | Result / observation |
|---|---|
| **Aerobic microbial growth** | No microbial growth detected |
| **Anaerobic microbial growth** | No growth detected |
| **Final determination** | No microbial growth detected during 14 day incubation period |

## METHOD OVERVIEW

The submitted sample was aseptically introduced into BacT ALERT culture bottles designed to support microbial growth detection. The BacT ALERT system continuously monitors each bottle during incubation. If microorganisms are present and grow, they may produce carbon dioxide which interacts with the colorimetric sensor in the bottle; the instrument detects this change photometrically. If growth is detected, the system automatically flags the bottle as positive and records the time to detection. If no growth is detected during the full incubation period, the final result is reported as no microbial growth detected.

## INTERPRETATION

No microbial growth was detected in the submitted sample during the 14 day BacT ALERT incubation period. The result indicates that no detectable microbial growth was observed under the conditions of this screening method. The result should not be interpreted as a guarantee of sterility for the entire batch lot or product line.

## AUTHORIZATION

| | | | |
|---|---|---|---|
| **Reviewed by** | Paul Molina | **Review date** | 9/26/26 |

