



## Certificate of Analysis

Date: 9/23/2026 Date Tested: 9/8/2026  
Customer: Peptides Optimized LLC Testing material: Sermorelin  
Batch #: SMO5-J18 BT Sample ID: PO-MEGRID  
Labeled Peptide 5 mg Storage: 2-8°C  
Content/Potency:  
Visual Description: Small clear vial: white lyophilized powder, silver crimp, black flip cap.  
Labeled as: Sermorelin Manufacturer: N/A  
Testing Purpose: FTIR and HPLC analysis for the identification, purity, potency and composition of a peptide product. It additionally reports elemental impurities (heavy metals), bacterial endotoxins and sterility as recorded in this certificate. It does not provide information on particulate matter.



| Test                                         | Method             | Specification                                          | Result                                                           | Status      |
|----------------------------------------------|--------------------|--------------------------------------------------------|------------------------------------------------------------------|-------------|
| General Appearance                           | Visual             | White to off-white powder                              | white powder                                                     | <b>PASS</b> |
| HPLC Purity of Peptide Assay                 | USP <621>          | NLT 98.0 % (area normalisation)                        | 99.8 %                                                           | <b>PASS</b> |
| HPLC Potency Assay                           | USP <621>          | 5 mg (net peptide), 90.0 - 110.0 %                     | 5.07 mg (101.4 %)                                                | <b>PASS</b> |
| Identity by Mass Spectrometry                | LC-MS (ESI)        | Observed mass within 1 Da of theoretical               | Conforms; observed mass matches Sermorelin reference standard.   | <b>PASS</b> |
| FTIR Identification and Composition Analysis | USP <197A>         | Sample spectrum consistent with the reference standard | FTIR spectrum consistent with the Sermorelin reference standard. | <b>PASS</b> |
| Heavy Metals (Elemental Impurities)          | USP <233> (ICP-MS) | Class 1 (Pb, Cd, As, Hg): NMT USP <232>/ICH Q3D limits | Complies (< LOQ)                                                 | <b>PASS</b> |

The results of the CoA relate only to the item(s) tested and applied to the sample as received.

COA # 2541410

ACCESS CODE **N3MNV27TZ4JB**

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**GB-QSA-TR001**  
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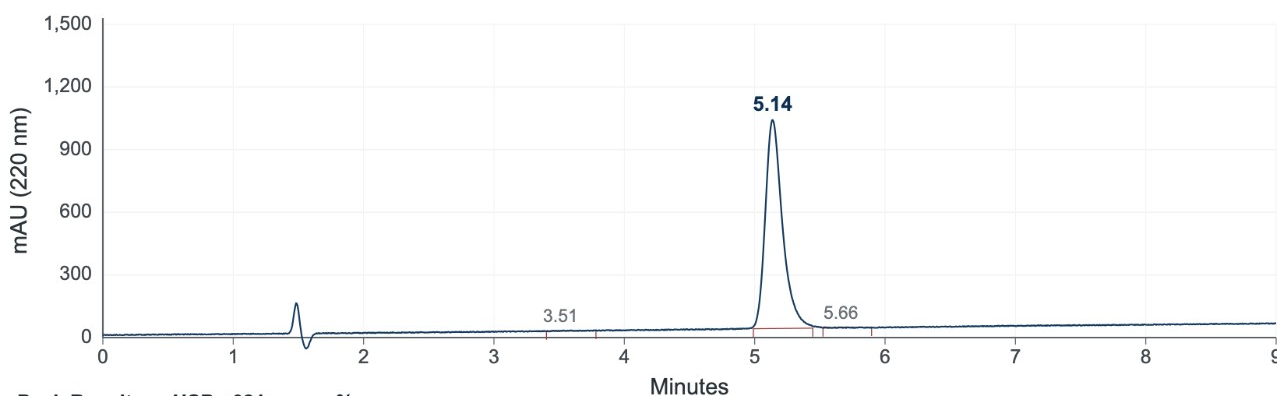
# Certificate of Analysis

**Product:** Sermorelin **Batch #:** SMO5-J18 **Content:** 5 mg **Tested:** 9/8/2026

## HPLC Purity Chromatogram @ 220 nm: Sermorelin Lot SMO5-J18

**Sample Name:** Sermorelin 5mg  
**Sample ID / Lot:** SMO5-J18  
**Method:** PEP\_TFA\_220\_GRAD.M  
**Column:** Zorbax SB-C18, 4.6 x 150 mm, 5 um  
**Signal:** VWD1 A, 220 nm  
**Mobile Phase:** A 0.1% TFA/H<sub>2</sub>O, B 0.1% TFA/MeCN (gradient)

**Injection Volume:** 10.0 uL  
**Acquired:** 9/8/2026 10:38  
**Vial:** 8 **Injection:** 1  
**Operator:** M.-J. Park  
**Flow:** 1.0 mL/min **Column Temp:** 30 C  
**System:** HPLC-04



### Peak Results - USP <621>, area %

| Pk           | RT (min) | Area (mAU*s) | Height (mAU) | Area %        | USP Res. | USP Tailing | USP Plates |
|--------------|----------|--------------|--------------|---------------|----------|-------------|------------|
| 1            | 3.51     | 9            | 1.3          | 0.10          | -        | -           | -          |
| 2            | 5.14     | 9,195        | 1,000        | 99.80         | 7.90     | 1.38        | 8,049      |
| 3            | 5.66     | 9            | 1.2          | 0.10          | -        | -           | -          |
| <b>Total</b> |          | <b>9,213</b> |              | <b>100.00</b> |          |             |            |

OpenLab CDS | Processing method: USP\_PURITY\_AREAPCT | Result: main peak 99.8 % (area) | Page 1 of 1



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## Heavy Metals Analysis (ICP-MS, USP <233>)

| Element       | Specification | Result       | Status |
|---------------|---------------|--------------|--------|
| Arsenic (As)  | NMT 1.5 ppm   | Not Detected | PASS   |
| Cadmium (Cd)  | NMT 0.5 ppm   | Not Detected | PASS   |
| Mercury (Hg)  | NMT 1.5 ppm   | Not Detected | PASS   |
| Lead (Pb)     | NMT 1 ppm     | Not Detected | PASS   |
| Chromium (Cr) | NMT 10 ppm    | Not Detected | PASS   |

Elemental impurities determined by ICP-MS. Limits are laboratory screening limits for research-use material, derived from ICH Q3D permitted daily exposures for the parenteral route.

| Test                      | Method   | Specification                | Result | Status |
|---------------------------|----------|------------------------------|--------|--------|
| Bacterial Endotoxins Test | USP <85> | NMT 40 EU/vial reconstituted | PASS   | PASS   |

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## Bacterial Endotoxins Test Sermorelin Lot SMO5-J18

| Sample ID | Description | Volume (mL) | Endotoxin Limit (EU/vial) | Lysate Sensitivity ( $\lambda$ , EU/mL) | Result       |
|-----------|-------------|-------------|---------------------------|-----------------------------------------|--------------|
| SMO5-J18  | Sermorelin  | 3           | 40 EU/vial                | 0.25                                    | 0.07 EU/vial |

The sample passed a valid gel clot endotoxin test based on the type, mode of administration and dosage.

## Sterility Test

| Test      | Method                            | Specification       | Result | Status |
|-----------|-----------------------------------|---------------------|--------|--------|
| Sterility | USP <71><br>(membrane filtration) | No microbial growth | PASS   | PASS   |

| Medium                              | Incubation Temp. | Duration | Units Tested | Observation |
|-------------------------------------|------------------|----------|--------------|-------------|
| Fluid Thioglycollate Medium (FTM)   | 30 – 35 °C       | 14 days  | 2            | No growth   |
| Soybean–Casein Digest Medium (SCDM) | 20 – 25 °C       | 14 days  | 2            | No growth   |

No microbial growth was observed. The sample meets the requirements of the sterility test (USP <71>).

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## Notes & Methodology

1. Peptide purity determined by RP-HPLC area normalisation at 220 nm. The value represents the percentage of the target peptide relative to all peptide-related peaks. Non-peptide process-related impurities, where detected, are excluded from the calculation.
2. Net peptide content (potency) calculated as assay content corrected for water (Karl Fischer) and counterion content, expressed as a percentage of the labelled claim.
3. Identity confirmed by FTIR against a reference standard (USP <197A>) and by chromatographic retention time comparison.
4. Elemental impurities screened by ICP-MS per USP <233> methodology. Acceptance criteria are laboratory screening limits for research-use material and do not constitute evaluation against a specific pharmacopoeial monograph.
5. Bacterial endotoxins determined by gel-clot method per USP <85>. Sterility per USP <71>.
6. The chromatogram reproduced in this certificate is representative of the batch tested.