**PrymaLab**
PRYMALAB ANALYTICAL · IN-HOUSE LABORATORY
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CERTIFICATE NO.
**PL-26-00309**
VERIFICATION KEY
**SNN6DXFW**
Scan or enter both at prymalab.net/testing/verify

CERTIFICATE OF ANALYSIS · LOT RELEASE

# SS-31 Elamipretide 10 mg Pen

Lot **PL-2610-196** · Solution · Label claim **10 mg/mL**

**TESTED IN-HOUSE BY PRYMALAB**
In-house analytical result, not an independent third-party test

| LOT / BATCH NUMBER | DATE MADE | DATE OF ANALYSIS | DATE ISSUED |
|---|---|---|---|
| PL-2610-196 | 2026-10-07 | 2026-10-08 | 2026-10-22 |
| **RETEST / EXPIRY** | **UNITS IN LOT / SAMPLED** | **STORAGE** | **CERTIFICATE TYPE** |
| 2028-10-07 | 193 / 2 | — | Lot COA, 2 pages |

**COMPOUND**
**SS-31**
Elamipretide (SS-31, MTP-131); D-Arg-Dmt-Lys-Phe-NH2

**SEQUENCE**
D-Arg-Dmt-Lys-Phe-NH2

**CAS NUMBER**
736992-21-5

**MOLECULAR FORMULA**
$C_{32}H_{49}N_9O_5$

**THEORETICAL MASS (AVG.)**
639.78 Da

PURITY · RP-HPLC, AREA %
**99.73%**
Specification ≥ 99.0 % • main peak at 8.95 min

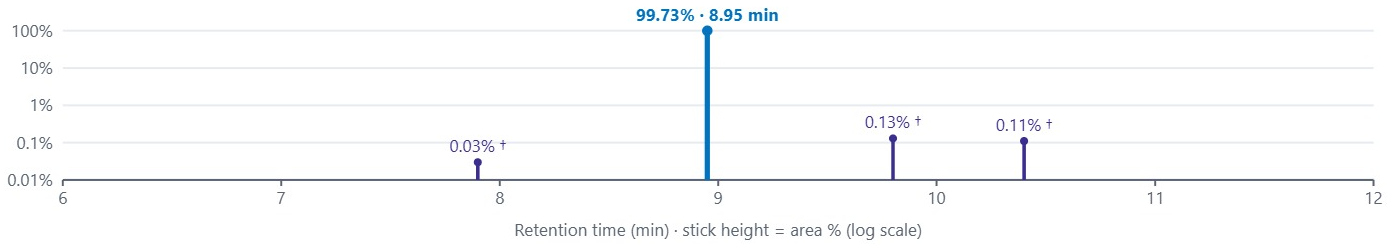
IDENTITY · OBSERVED MASS
**639.75 Da**
Theoretical 639.78 Da • −0.03 Da (47 ppm)

OVERALL CONCLUSION
**PASS**
Meets every specification for the tests performed

| TEST | METHOD | SPECIFICATION | RESULT | CONCLUSION |
|---|---|---|---|---|
| **Identity (mass)** | LC-MS, ESI positive | Theoretical ± 1.0 Da | 639.75 Da | PASS |
| **Purity** | RP-HPLC, UV 214 nm, area % | ≥ 99.0 % | 99.73 % | PASS |
| **Largest impurity** | RP-HPLC, area % | ≤ 1.0% | 0.13% (RT 9.80) | PASS |
| **Assay (label claim)** | Assay vs label claim | 9.5–10.5 mg/mL | 9.80 mg/mL | PASS |
| **Bacterial endotoxin** | LAL, kinetic | ≤ 5.0 EU/mg | 0.285 EU/mg | PASS |
| **Sterility** | USP <71>, 14-day | No growth | No growth | PASS |

## 1 HPLC CHROMATOGRAM

**Data file:** PL-2610-196-HPLC.raw · Column C18, 150 × 4.6 mm · UV 214 nm




Peak plot drawn from the integrated peak table (area %, log scale); it is not the instrument trace, which is retained in PL-2610-196-HPLC.raw. † Nominal reference retention time for the assigned impurity; the main-peak RT is observed in this lot.


**For laboratory research use only.** Not for human or veterinary use.

## 2 HPLC METHOD · PL-2610-196-HPLC.RAW

**INSTRUMENT**
Waters Alliance e2695

**DATA SYSTEM**
Empower 3

**DETECTOR**
UV absorbance

**DETECTION WAVELENGTH**
214 nm

**COLUMN**
C18, 150 × 4.6 mm, 3.5 µm

**MOBILE PHASE A**
0.1 % TFA in water

**MOBILE PHASE B**
0.1 % TFA in MeCN

**GRADIENT**
5–95 % B over 25 min (linear)

**FLOW RATE**
1.0 mL/min

**COLUMN TEMPERATURE**
40 °C

**INJECTION VOLUME**
10 µL

## 3 GRADIENT PROGRAM

| TIME (MIN) | % A | % B |
|---|---|---|
| 0.0 | 95 | 5 |
| 25.0 | 5 | 95 |

## 4 PEAK TABLE

| PEAK | RT (MIN) | AREA | AREA % |
|---|---|---|---|
| 1 | 7.90 † | — | 0.03 |
| **2** | **8.95** | **—** | **99.73** |
| 3 | 9.80 † | — | 0.13 |
| 4 | 10.40 † | — | 0.11 |
| Total | | — | 100.00 |

Peaks: 1 unidentified impurity; 2 main peak (SS-31); 3 unidentified impurity; 4 unidentified impurity · Area % from the integrated peak table (absolute areas are not part of the lot-release export) · † nominal reference RT for the assigned impurity · Purity = main peak area ÷ total integrated area × 100, to two decimals; main peak shaded.

## 5 IDENTITY BY MASS SPECTROMETRY

**INSTRUMENT**
Waters SQD

**IONIZATION / MODE**
ESI, positive

**REFERENCE M/Z (CHARGE)**
640.79 (M+H)+

**DECONVOLUTED MASS**
639.75 Da

**THEORETICAL MASS**
639.78 Da

**DIFFERENCE**
−0.03 Da (47 ppm)

**DATA FILE**
PL-2610-196-MS.d

**ACCEPTANCE**
Within ± 1.0 Da

## 6 ADDITIONAL TESTS

| TEST | PERFORMED BY | DATE | REPORT / FILE |
|---|---|---|---|
| Assay vs label claim | PrymaLab Analytical | 2026-10-08 | — |
| Endotoxin (LAL, kinetic) | PrymaLab Analytical | 2026-10-08 | — |
| Sterility (USP <71>, day-14 read-out) | PrymaLab Analytical | 2026-10-22 | — |

A test with no row here was not performed on this lot. Outside-laboratory reports, when used, are attached and named below.

## 7 REVIEW AND APPROVAL

**D. Reynolds**
Analyst · performed the testing
Date: 2026-10-22

**S. Calloway**
Reviewer · checked against raw data
Date: 2026-10-22

**M. Phelps**
Lab Director · approved for release
Date: 2026-10-22

Raw data retained at: Empower 3, project PL-2610, archive PL-ARC-2026; 7 years. Outside laboratory reports attached: None

This certificate applies only to the lot named above and describes the units sampled from it; it is not a guarantee for any other lot. Results were obtained by PrymaLab LLC's own laboratory (PrymaLab Analytical) and are not an independent third-party test unless an outside report is attached. Reference values (CAS, formula, theoretical mass, sequence) are literature values for the named compound. Authenticity: scan the QR code or enter certificate number PL-26-00309 and key SNN6DXFW at prymalab.net/testing/verify; any copy that does not match the record shown there is not a PrymaLab certificate. PrymaLab LLC products are supplied for laboratory research use only and not for human or veterinary use.