

ALC-PROOF-TESAMORELIN-10-44 · Rev 1

**Catalog reference:** tesamorelin-10

**Search code:** ALC-PROOF-TESAMORELIN-10-44

**Received:** 2026-09-28

**Analyzed:** 2026-09-29

**Reported:** 2026-09-30

**Lot:** SYN-00044

### Sample Summary

**Product:** Tesamorelin - 10 mg

**Principal peak purity:** 99.59 % (area)

**Identity evidence:** Mass assignment supplied

**Net content:** 9.796 mg

**Molecular formula:** C221H366N72O67S

**Neutral mass:** 5,132.71664 Da (monoisotopic; calculated)

**Appearance:** Lyophilized material

**Chemical reference:** [PubChem CID 16137828](#)

### Analytical Results

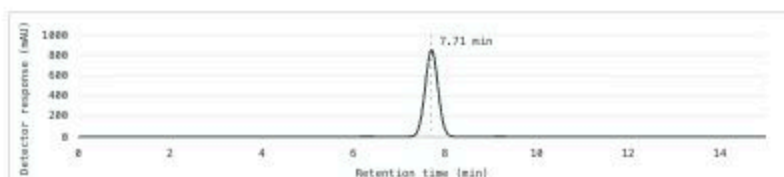
Review required

Profile profile-tesamorelin-10 v1.

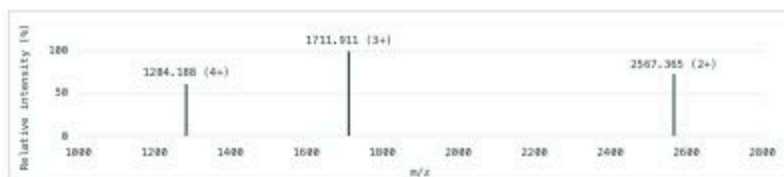
| Determination / method                                                                                  | Result                         | Specification | Decision           |
|---------------------------------------------------------------------------------------------------------|--------------------------------|---------------|--------------------|
| <b>Principal peak purity</b><br>HPLC-01 · area basis<br>Peak area percent. This is not a mass fraction. | 99.59 %<br>U = 0.08 %, k = 2   | 98 to 100 %   | Pass<br>simple     |
| <b>Net content</b><br>QNT-01 · mass basis<br>Specification applies to the declared label claim.         | 9.796 mg<br>U = 0.15 mg, k = 2 | 9 to 11 mg    | Pass<br>guard-band |

Methods: Quantitative assay; RP-HPLC with UV detection; LC-MS mass assignment. Conditions, limits and calculated checks are included in the supporting pages.

### Chromatogram



### Mass Confirmation



| Charge state | m/z (observed) | Mass error (ppm) |
|--------------|----------------|------------------|
| [M+2H]2+     | 2567.36537     | -0.09            |
| [M+3H]3+     | 1711.91149     | -0.78            |
| [M+4H]4+     | 1284.18825     | 1.41             |

monoisotopic mass convention; configured tolerance 10 ppm. Full acquisition values follow.

*Paul Gütse*

Paul Gütse  
Reviewed by

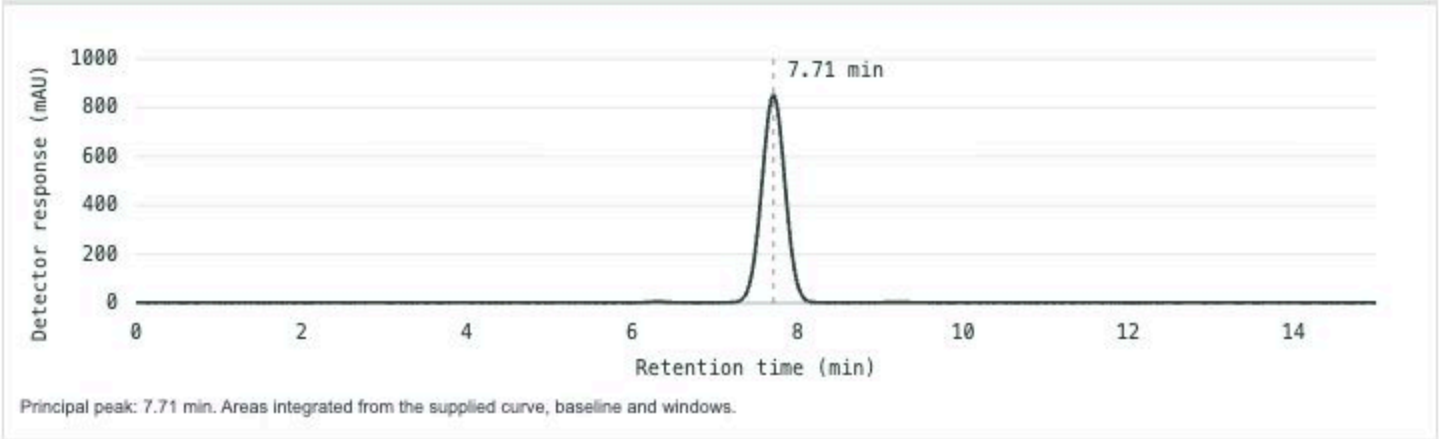
Scan report code  
Local design proof  
ALC-PROOF-TESAMORELIN-10-44



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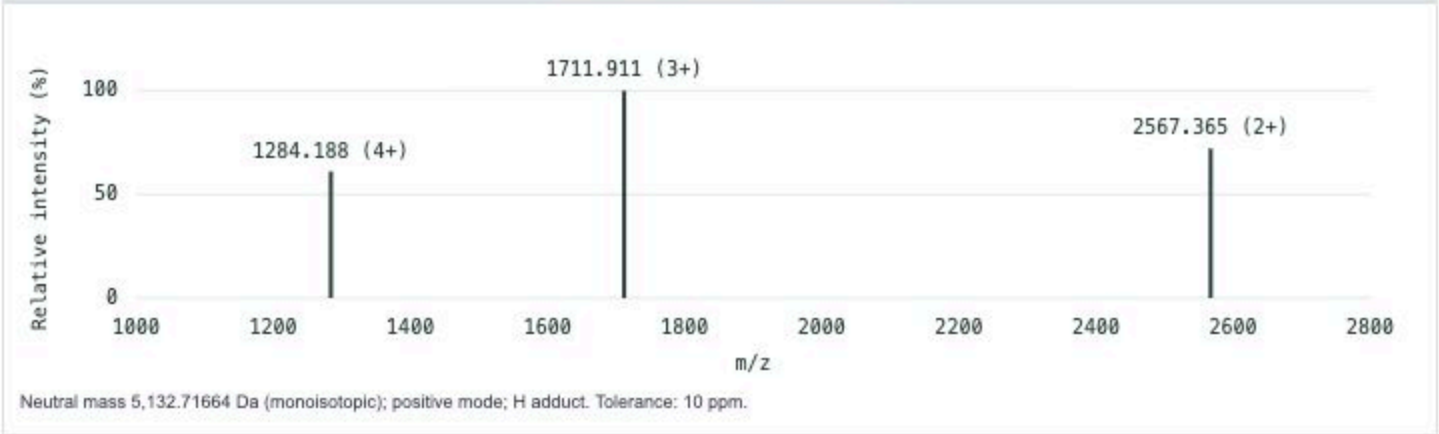
Results apply only to the submitted sample and the methods listed in this report. Only the listed methods are covered. This report does not establish sterility, endotoxin content, biological activity or suitability for clinical use.

Chromatographic evidence

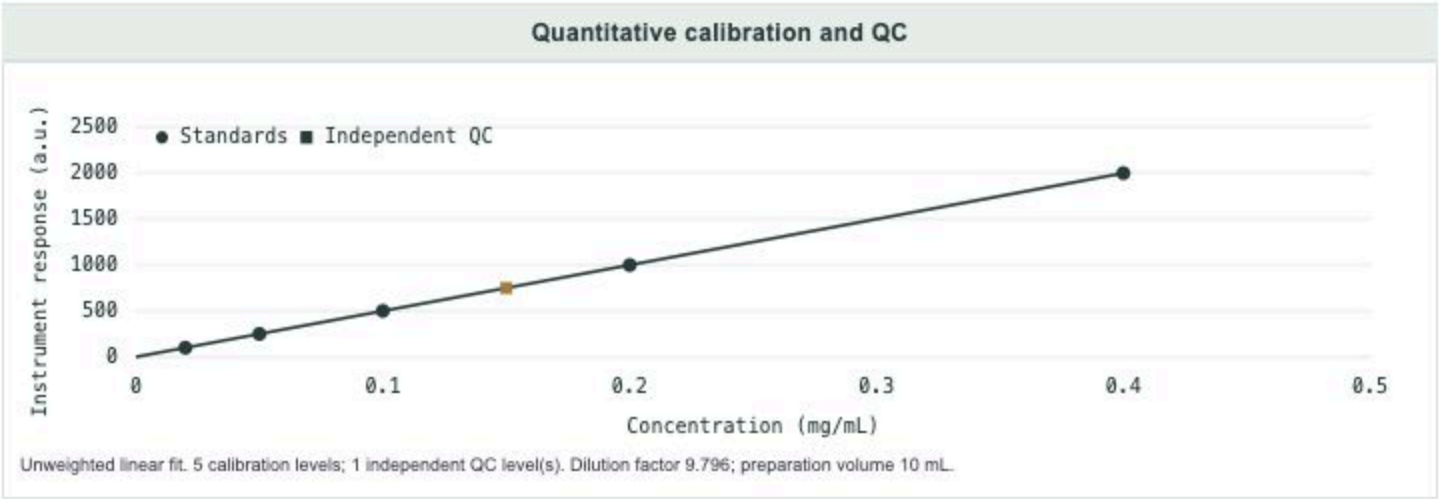


| Integrated peak | Area (detector unit x min) | Area % |
|-----------------|----------------------------|--------|
| Principal peak  | 281.32537                  | 99.59  |
| Early impurity  | 0.76658                    | 0.27   |
| Late impurity   | 0.40238                    | 0.14   |

Mass spectrometric evidence



| Charge | Observed m/z | Predicted m/z | Error (ppm) |
|--------|--------------|---------------|-------------|
| 2+     | 2567.36537   | 2567.36560    | -0.09       |
| 3+     | 1711.91149   | 1711.91282    | -0.78       |
| 4+     | 1284.18825   | 1284.18644    | 1.41        |



| Calculated checks and system suitability |                |                                                 |               |
|------------------------------------------|----------------|-------------------------------------------------|---------------|
| Analysis check                           | Value          | Configured criterion                            | Assessment    |
| Expected neutral monoisotopic mass       | 5132.716641 Da | Chemical reference                              | informational |
| Principal peak purity                    | 99.59 % area   | Minimum 98; caution below 99                    | pass          |
| Assay relative to label claim            | 97.96 %        | 90 to 110                                       | pass          |
| Total integrated impurities              | 0.4138 % area  | Maximum 2                                       | pass          |
| Largest integrated impurity              | 0.2714 % area  | Maximum 1.5                                     | pass          |
| Retention time                           | 7.71 min       | 7.71 +/- 0.2                                    | pass          |
| Principal peak width at half height      | 0.3118 min     | 0.3109 +/- 30%                                  | pass          |
| Theoretical plates                       | 3387           | Minimum 2000                                    | pass          |
| Resolution to Early impurity             | 3.303          | Minimum 1.5                                     | pass          |
| Resolution to Late impurity              | 3.421          | Minimum 1.5                                     | pass          |
| Tailing factor at 5% height              | 1.032          | Maximum 2                                       | pass          |
| Principal signal to baseline noise       | 19170.5        | Minimum 50                                      | pass          |
| Calibration R squared                    | 0.999999       | Minimum 0.995                                   | pass          |
| Independent QC bias                      | -0.058 %       | Absolute maximum 5                              | pass          |
| Calibration-derived content              | 9.796 mg       | Agrees with reported content within uncertainty | informational |

Assessment observations

WARNING · impurity-detected

Early impurity: 0.271% area meets the configured impurity reporting threshold 0.05%.

WARNING · impurity-detected

Late impurity: 0.142% area meets the configured impurity reporting threshold 0.05%.

## Methods and decision rules

## QNT-01 · Quantitative assay 1

**Instrument:** analytical balance

Calibration and replicate measurement. Expanded uncertainty uses  $k = 2$ .

Expanded measurement uncertainty uses a coverage factor of 2.

## HPLC-01 · RP-HPLC with UV detection 1

**Instrument:** HPLC-UV

C18 column, 150 x 4.6 mm, 5  $\mu$ m; 0.1% formic acid in water/acetonitrile; 5 to 60% B over 15 min; 1.0 mL/min; 25 C; 214 nm; 10  $\mu$ L injection.

Trapezoidal integration against the declared baseline and windows.

## MS-01 · LC-MS mass assignment 1

**Instrument:** ESI mass spectrometer

Positive ionization; protonated species; monoisotopic mass convention.

Neutral analyte formula: linked PubChem reference.

Simple acceptance compares the result with the stated limits. Guard band acceptance requires the full expanded uncertainty interval to fall within the limits; overlap is indeterminate. A failed specification remains a reportable result.

## Scope and observations

Calculated from the configured neutral formula using monoisotopic atomic masses. This is a theoretical value, not an observed MS result.

Only the listed methods are covered. This report does not establish sterility, endotoxin content, biological activity or suitability for clinical use.

Sample reference: Catalog identity and nominal content supplied by the client.

Chemical form: Neutral tesamorelin analyte

Chemical reference: [PubChem CID 16137828](#)

Prepared by: alchemlabs