

Certificate of Analysis

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Sample Identification

Sample Name Tesamorelin 10 mg
Batch Number 0012924
Date Published 2026-06-22 12:41

Results for LYO-0279

| Peptides | Result | Unit | Uncertainty | Acceptable Range |
|--|---------|-------|-------------|------------------|
| Tesamorelin Assay Peptide Screening 0.1% TFA | 9.44 | mg | [± 0.05] | |
| Tesamorelin Purity Peptide Screening 0.1% TFA | > 99.8 | % | | |
| Tesamorelin Identification by Spectrum Peptide Screening 0.1% TFA | 997 | | [± 5] | |
| Tesamorelin Identification by RT Peptide Screening 0.1% TFA | 0.999 | | [± 0.005] | |
| Microbiology | Result | Unit | Uncertainty | Acceptable Range |
| Bacterial Endotoxin Chromgenic USP<85>/ Eur. Ph. 2.6.14. Bacterial Endotoxin Chromgenic Test | < 0.001 | EU/mg | | 0 - 0.5 |

| | | |
|---|---------------------------------|-----------------------------|
|  | Method Specification | |
| Determination of identity, content and purity of Tesamorelin | | |
| <i>Document number</i> TESA_006_2026 | <i>Superseded document</i> - | <i>Number of pages</i> 3 |

1. Content Assesment

1.1. Instrumentation

| Module | Name | Serial Number |
|-------------------|----------------------|---------------|
| System Controller | Shimadzu CBM-40 Lite | L221226351398 |
| Degassing Unit | Shimadzu DGU-403 | NA |
| Pump | Shimadzu LC-40B XR | L22146350580 |
| Autosampler | Shimadzu SIL-40C XR | L22216351622 |
| Colum Thermostat | Shimadzu CTO-40S | L22236351602 |
| PDA Detector | Shimadzu SPD-M40 | L22276352808 |
| SQ MS Detector | Shimadzu LCMS-2050 | O12476200760 |

1.2. Chromatographic conditions

| Chromatographic conditions | |
|----------------------------|--|
| Eluent A | 0.05% TFA in Water (HPLC, Gradient Grade) |
| Eluent B | 0.05% TFA in Acetonitrile (HPLC, Gradient Grade) |
| Flow rate | 0.9 mL/min |
| Program | Gradient elution |
| Injection volume | 2 µL |
| Colum Temperature | 55°C |
| Column | Waters XSelect CSH C18, 100x2.1mm 2.5µm |
| Detection wavelength | 280nm |

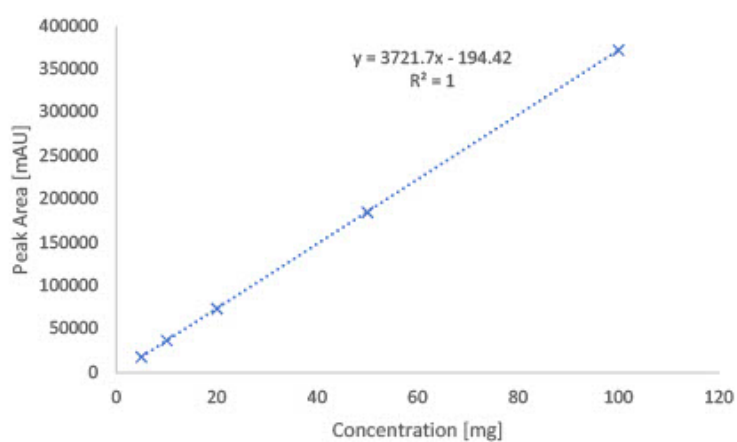
| Gradient Program | | |
|------------------|-------|-------|
| Time [min] | A [%] | B [%] |
| 1.5 | 95 | 5 |
| 13 | 45 | 55 |
| 13.5 | 1 | 99 |
| 14.5 | 1 | 99 |
| 14.51 | 95 | 5 |
| 16 | end | |

1.3. Sample preparation

Whole amount of container was dissolved in 2mL of water (LCMS Grade). 100 µL of sample was transferred to HPLC vial and diluted by 900 µL water (LCMS Grade) and submitted for analysis.

1.4. Calibration curve

| Calibration curve detail | |
|------------------------------|-------------------|
| Quantitative method | External Standard |
| Calibration Type | Linear |
| Number of calibration points | 5 |
| Force through Zero | Enabled |
| Weighting Method | None |



2. Purity assessment

2.1 Instrumentation

| Module | Name | Serial Number |
|-------------------|----------------------|---------------|
| System Controller | Shimadzu CBM-40 Lite | L221226351398 |
| Degassing Unit | Shimadzu DGU-403 | NA |
| Pump | Shimadzu LC-40B XR | L22146350580 |
| Autosampler | Shimadzu SIL-40C XR | L22216351622 |
| Colum Thermostat | Shimadzu CTO-40S | L22236351602 |
| PDA Detector | Shimadzu SPD-M40 | L22276352808 |
| SQ MS Detector | Shimadzu LCMS-2050 | O12476200760 |

2.2 Chromatographic conditions

| Chromatographic conditions | |
|----------------------------|--|
| Eluent A | 0.05% TFA in Water (HPLC, Gradient Grade) |
| Eluent B | 0.05% TFA in Acetonitrile (HPLC, Gradient Grade) |
| Flow rate | 0.9 mL/min |
| Program | Gradient elution |
| Injection volume | 2 µL |
| Colum Temperature | 55°C |
| Column | Waters XSelect CSH C18, 100x2.1mm 2.5µm |
| Detection wavelength | 225nm |

| Gradient Program | | |
|------------------|-------|-------|
| Time [min] | A [%] | B [%] |
| 1.5 | 95 | 5 |
| 13 | 45 | 55 |
| 13.5 | 1 | 99 |
| 14.5 | 1 | 99 |
| 14.51 | 95 | 5 |
| 16 | end | |

2.3 Purity assesment

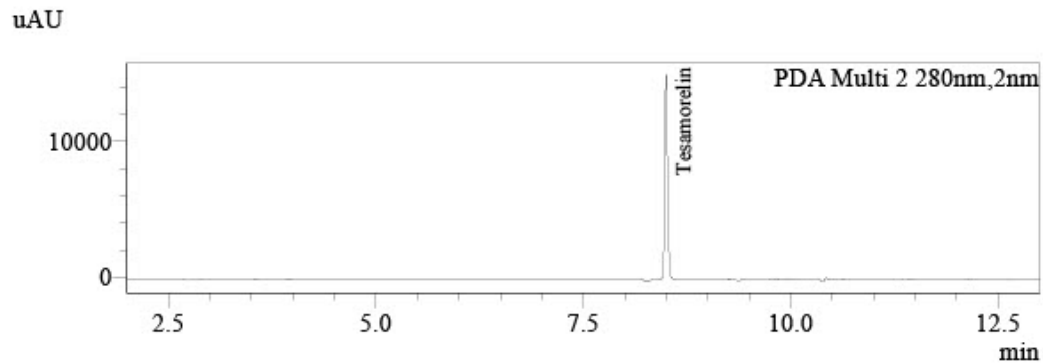
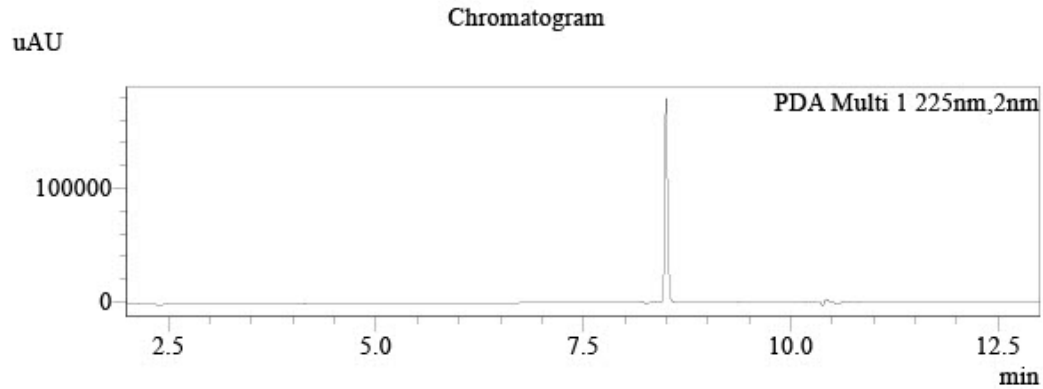
Purity of compound assesed by area normalization method, comparing area of each peak to sum of area of all peaks detected at wavelenght of 214 nm.

Analysis Report



Analysis of quantity and purity of active ingredient by UHPLC with UV detection

Sample Information
Injection Volume : 2
Data File : LYO-0279_039.lcd
Method File : Peptide screening_V7_Group B.lcm
Date Acquired : 6/19/2026 11:33:53 AM



Peak Table

| PDA Ch1 225nm | | | | | |
|---------------|-----------|--------|-------|------|---------|
| Name | Ret. Time | Area | Conc. | Unit | Area% |
| | 8.496 | 417812 | 0.000 | | 100.000 |
| | | 417812 | | | 100.000 |

Peak Table

| PDA Ch2 280nm | | | | | |
|---------------|-----------|-------|-------|------|--|
| Name | Ret. Time | Area | Conc. | Unit | |
| Tesamorelin | 8.496 | 34927 | 9.437 | mg | |
| | | 34927 | | | |

Endotoxin Determination Report

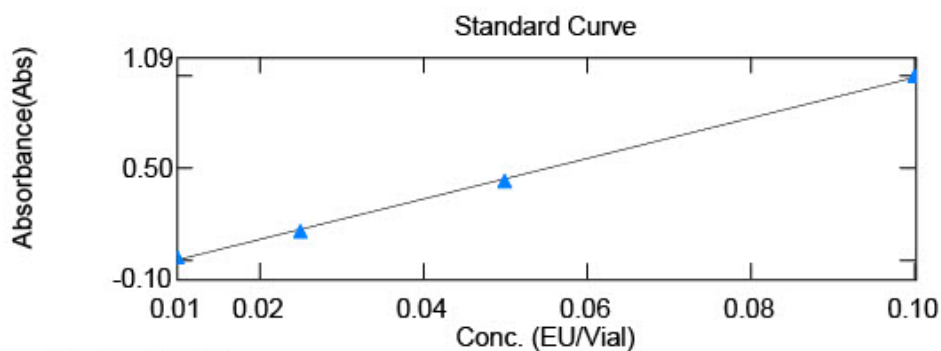


File Information

Filename: C:\UVVis-Data\Data\File_260618.vqud
Date/Time: 06/18/2026 08:15:51 PM

Instrument Information

Instrument Type: UV-1900 Series
Model (S/N): UV-1900i (A12536253123)



$$y = 10.9261x - 0.105573$$
$$r^2 = 0.99912$$

| | Sample Name | Conc | Raw_WL545.0 | Result |
|----|-------------|-------|-------------|--------|
| 1 | LYO-0244 | 0.044 | 0.1330 | 0.133 |
| 2 | LYO-0247 | 0.011 | -0.0463 | -0.046 |
| 3 | LYO-0248 | 0.010 | -0.0523 | -0.052 |
| 4 | LYO-0249 | 0.010 | -0.0502 | -0.050 |
| 5 | LYO-0250 | 0.014 | -0.0268 | -0.027 |
| 6 | LYO-0251 | 0.025 | 0.0285 | 0.029 |
| 7 | LYO-0252 | 0.023 | 0.0182 | 0.018 |
| 8 | LYO-0253 | 0.011 | -0.0475 | -0.047 |
| 9 | LYO-0259 | 0.013 | -0.0331 | -0.033 |
| 10 | LYO-0260 | 0.012 | -0.0379 | -0.038 |
| 11 | LYO-0261 | 0.012 | -0.0423 | -0.042 |
| 12 | LYO-0262 | 0.415 | 2.1602 | 2.160 |
| 13 | LYO-0272 | 0.023 | 0.0190 | 0.019 |
| 14 | LYO-0278 | 0.018 | -0.0050 | -0.005 |
| 15 | LYO-0279 | 0.018 | -0.0065 | -0.007 |

Responsibles



Mr. Ján Galbavý
CEO

Analysis results relate only to the samples tested.

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