

Certificate Of Analysis

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Sample Identification

Sample Name Tesamorelin 10 mg **Batch Number** **Date Published** 2026-01-30 13:19

Results for Lyo-0253

**Analysis of Peptide Identity,
Content and Purity**

Tesamorelin Assay

Result	Unit
9.41	<i>mg</i>

**Reporting
UncertaintyLimit**

[± 0.05]

Peptide Screening

0.999

[± 0.005]

Tesamorelin Identification

by RT

999

[± 20]

Peptide Screening

Tesamorelin Identification

by spectrum

99.1 %


[± 0.5]

Peptide Screening

Tesamorelin Purity

Peptide Screening

Attachments for Lyo-0253

	Method Specification	
Determination of identity, content and purity of Tesamorelin		
<i>Document number</i> TESA_010_2025	<i>Superseded document</i> -	<i>Number of pages</i> 3

1. Content Assesment

1.1. Instrumentation

Module	Name	Serial Number
System Controller	Shimadzu SCL-10ADvp	C21014112659
Degassing Unit	Shimadzu DGU-14A	NA
Pump A	Shimadzu LC-10ADvp	C20964130075
Pump B	Shimadzu LC-10ADvp	C20953770781
Autosampler	Shimadzu SIL-10ADvp	C21054109114
Colum Thermostat	Shimadzu CTO-10ACvp	C21033770144
Detector	Shimadzu SPD-10ADvp	C20994233588

1.2. Chromatographic conditions

Chromatographic conditions	
Eluent A	0.1% TFA in Water (HPLC, Gradient Grade)
Eluent B	0.1% TFA in Acetonitrile (HPLC, Gradient Grade)
Flow rate	0.4 mL/min
Program	Gradient elution
Injection volume	0.5 µL
Colum Temperature	60°C
Column	Phenomenex Biozen Peptide Polar C18, 150x2.1mm 3µm
Detection wavelenght	214nm

Gradient Program		
Time [min]	A [%]	B [%]
1	95	5
19	40	60
20	5	95
24	5	95
25	95	5
33	end	

1

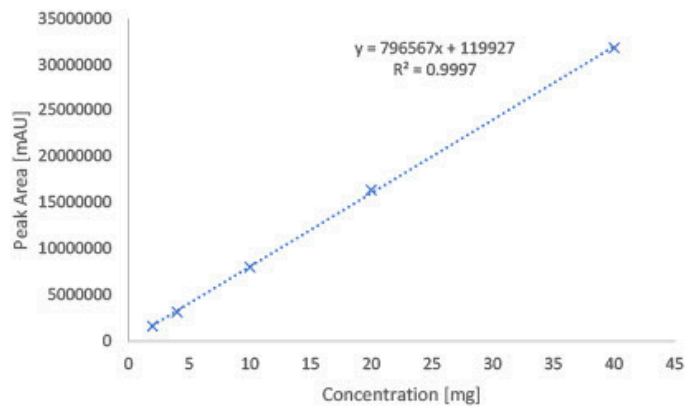
Attachment for Lyo-0253
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1.3. Sample preparation

Whole amount of container was dissolved in 2mL of water (HPLC, Gradient Grade). Aliquote part of 1 mL was dispensed into HPLC vial for analysis.

1.4. Calibration curve

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



2. Purity assessment

2.1 Instrumentation

Module	Name	Serial Number
System Controller	Shimadzu SCL-10ADvp	C21014112659
Degassing Unit	Shimadzu DGU-14A	NA
Pump A	Shimadzu LC-10ADvp	C20964130075
Pump B	Shimadzu LC-10ADvp	C20953770781
Autosampler	Shimadzu SIL-10ADvp	C21054109114
Column Thermostat	Shimadzu CTO-10ACvp	C21033770144
Detector	Shimadzu SPD-10ADvp	C20994233588

2.2 Chromatographic conditions

Chromatographic conditions	
Eluent A	0.1% TFA in Water (HPLC, Gradient Grade)
Eluent B	0.1% TFA in Acetonitrile (HPLC, Gradient Grade)
Flow rate	0.4 mL/min
Program	Gradient elution
Injection volume	0.5 µL
Column Temperature	60°C
Column	Phenomenex Biozen Peptide Polar C18, 150x2.1mm 3µm
Detection wavelength	214nm

Gradient Program		
Time [min]	A [%]	B [%]
1	95	5
19	40	60
20	5	95
24	5	95
25	95	5
33	end	

2.3 Sample preparation

Whole amount of container was dissolved in 2mL of water (HPLC, Gradient Grade). Aliquote part of 1 mL was dispensed into HPLC vial for analysis.

2.4 Purity assesment

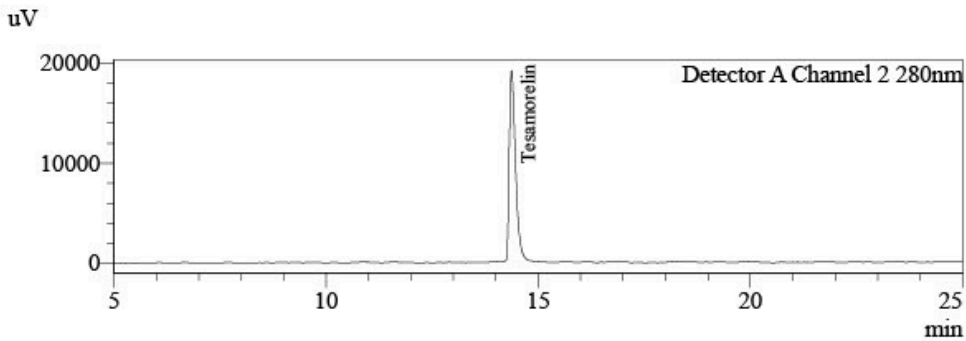
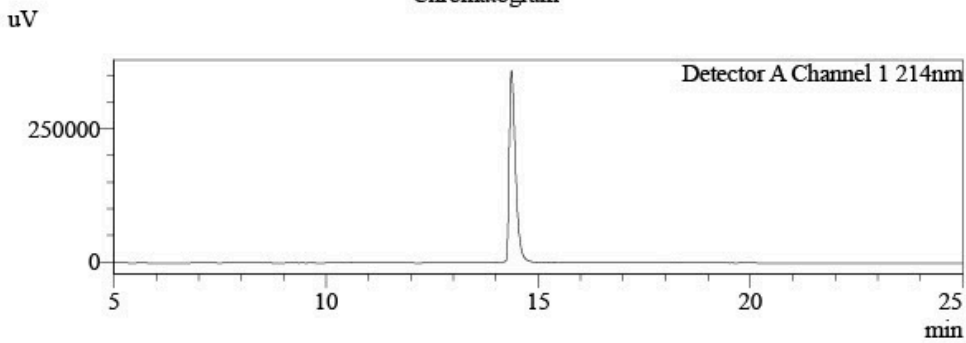
Purity of compound assesed by area normalization method, comparing area of each peak to sum of area of all peaks detected at wavelength of 214 nm.

Analysis Report



Sample Information
Injection Volume : 0,5
Data File : LYO-0253_001.lcd
Method File : Peptide screening_Group D.lcm
Date Acquired : 30.01.2026 13:28:49

Chromatogram



Peak Table

Detector A Channel 1 214nm

Peak#	Name	Ret. Time	Conc.	Unit	Area%
1		14,204	0,000		0,426
2		14,371	0,000		99,075
3		18,209	0,000		0,498
Total					100,000

Peak Table

Detector A Channel 2 280nm

Peak#	Name	Ret. Time	Conc.	Unit
1	Tesamorelin	14,372	9,406	mg/L
Total				

Attachment for Lyo-0253
Filename: LYO-0253.jpg

Responsibles



Mr. Ján Galbavý
Founder/Manager

Analysis results relate only to the samples tested.

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