

Certificate of Analysis

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Sample Identification

Sample Name Sermorelin 10 mg
Batch Number 1320227
Date Published 2026-06-08 13:17

Results for LYO-0203

Peptides	Result	Unit	Uncertainty	Acceptable Range
Sermorelin Assay Peptide Screening 0.1% TFA	10.50	mg	[± 0.05]	
Sermorelin Purity Peptide Screening 0.1% TFA	99.7	%	[± 0.5]	
Sermorelin Identification by Spectrum Peptide Screening 0.1% TFA	996		[± 5]	
Sermorelin Identification by RT Peptide Screening 0.1% TFA	0.998		[± 0.005]	

	Method Specification	
Determination of identity, content and purity of Sermorelin		
<i>Document number</i> SERM_006_2026_QT	<i>Superseded document</i> -	<i>Number of pages</i> 2

1. Content Assessment

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	225nm

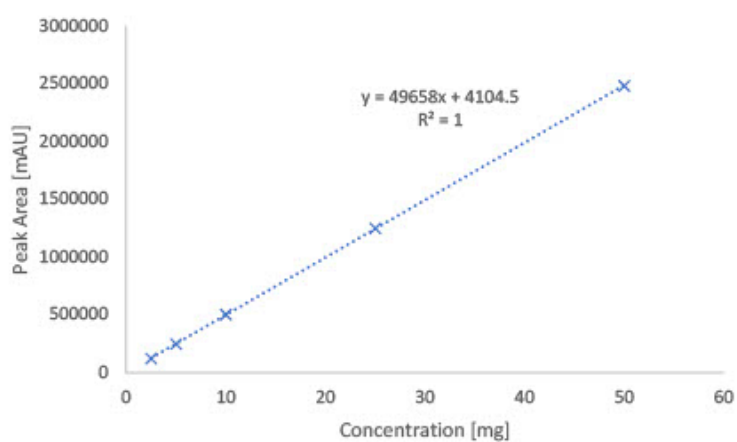
Gradient Program		
Time [min]	A [%]	B [%]
1.5	95	5
13	45	55
13.5	1	99
14.5	1	99
14.51	95	5
16	end	

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

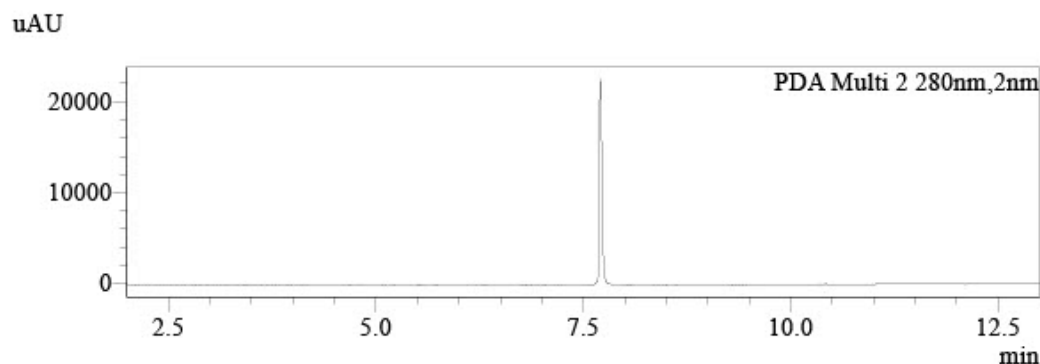
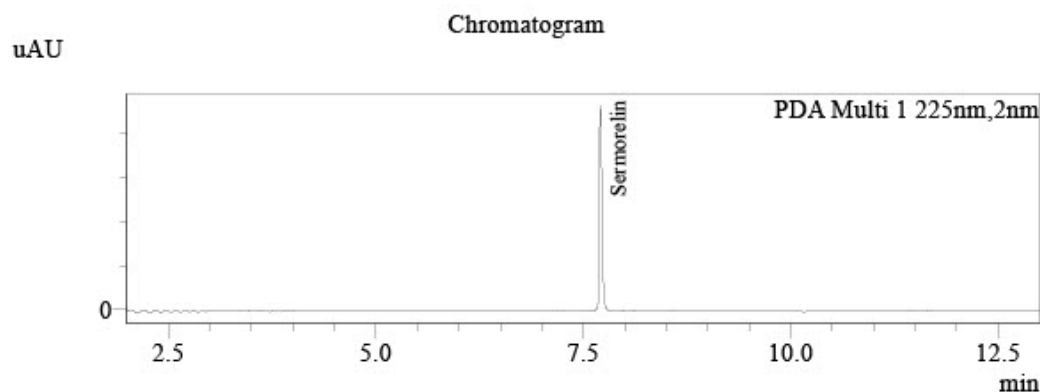
Purity of compound assesed by area normalization method, comparing area of each peak to sum of area of all peaks detected at wavelenght of 214 nm.

Analysis Report



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

Sample Information
Injection Volume : 2
Data File : LYO-0203_014.lcd
Method File : Peptide screening_V6_QT_QC_B.lcm
Date Acquired : 6/3/2026 12:26:17 AM



Peak Table

PDA Ch1 225nm

Name	Ret. Time	Area	Conc.	Unit	Area%
	7.566	297	0.000		0.057
Sermorelin	7.706	522591	10.499	mg	99.704
	8.430	181	0.000		0.035
	8.567	560	0.000		0.107
	8.681	223	0.000		0.043
	8.817	288	0.000		0.055
		524140			100.000

Peak Table

PDA Ch2 280nm

Name	Ret. Time	Area	Conc.	Unit
	7.706	50403	0.000	
		50403		

Responsibles



Mr. Ján Galbavý
CEO

Analysis results relate only to the samples tested.

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