

Certificate of Analysis

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Sample Identification

Sample Name Tesamorelin
Batch Number XD-TSM10-PO07
Date Published 2026-09-08 05:07

Results for LYO-0773

Peptides	Result	Unit	Uncertainty	Acceptable Range
Tesamorelin Assay Peptide Screening 0.1% TFA	8.24	mg	[± 0.04]	
Tesamorelin Purity Peptide Screening 0.1% TFA	99.4	%	[± 0.5]	
Tesamorelin Identification by Spectrum Peptide Screening 0.1% TFA	980		[± 5]	
Tesamorelin Identification by RT Peptide Screening 0.1% TFA	0.998		[± 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		

	Method Specification		
Determination of identity, content and purity of Tesamorelin			
<i>Document number</i> TESA_008_2026	<i>Superseded document</i> -	<i>Number of pages</i> 4	

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	0.1% DFA in Water (HPLC, Gradient Grade)
Eluent B	0.1% DFA in Acetonitrile (HPLC, Gradient Grade)
Flow rate	0.8 mL/min
Program	Gradient elution
Injection volume	2 µL
Colum Temperature	60°C
Column	Waters XSelect CSH C18, 100x2.1mm 2.5µm
Detection wavelength	280nm

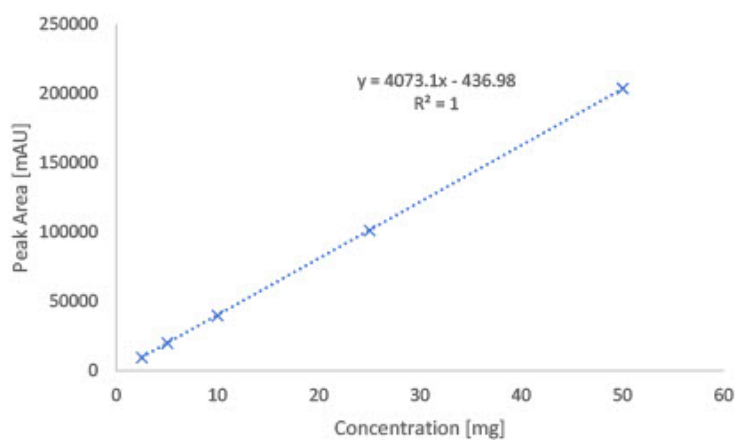
Gradient Program		
Time [min]	A [%]	B [%]
1	98	2
13.99	35	65
14	5	95
15	5	95
15.01	98	2
19	end	

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	0.1% DFA in Water (HPLC, Gradient Grade)
Eluent B	0.1% DFA in Acetonitrile (HPLC, Gradient Grade)
Flow rate	0.8 mL/min
Program	Gradient elution
Injection volume	2 µL
Colum Temperature	60°C
Column	Waters XSelect CSH C18, 100x2.1mm 2.5µm
Detection wavelength	225nm

Gradient Program		
Time [min]	A [%]	B [%]
1	98	2
13.99	35	65
14	5	95
15	5	95
15.01	98	2
19	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 225 nm.

Analysis Report



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Analytical services

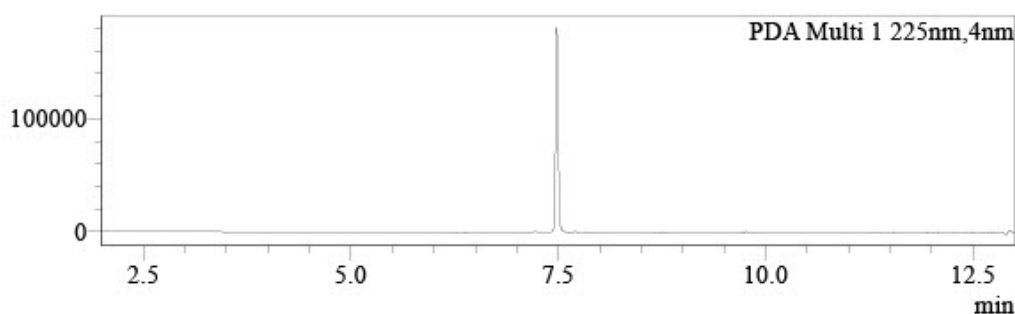
Analysis of quantity and purity of active ingredient by UHPLC with UV detection

Sample Information

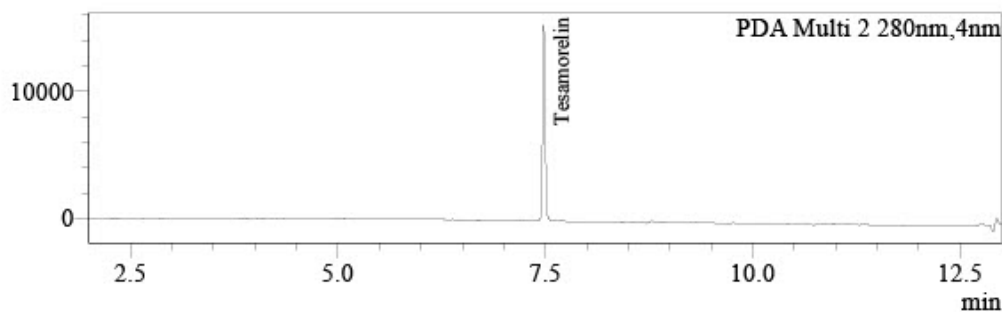
Injection Volume : 2
Data File : LYO-0773__016.lcd
Method File : Peptide Screening_DFA_Group B.lcm
Date Acquired : 9/4/2026 2:51:10 AM

Chromatogram

uAU



uAU



Peak Table

PDA Ch1 225nm

Name	Ret. Time	Area	Conc.	Unit	Area%
	7.216	1097	0.000		0.278
	7.481	392318	0.000		99.414
	7.700	945	0.000		0.240
	7.848	269	0.000		0.068
		394628			100.000

Peak Table

PDA Ch2 280nm

Name	Ret. Time	Area	Conc.	Unit
Tesamorelin	7.480	33129	8.241	mg
		33129		

Endotoxin Determination Report

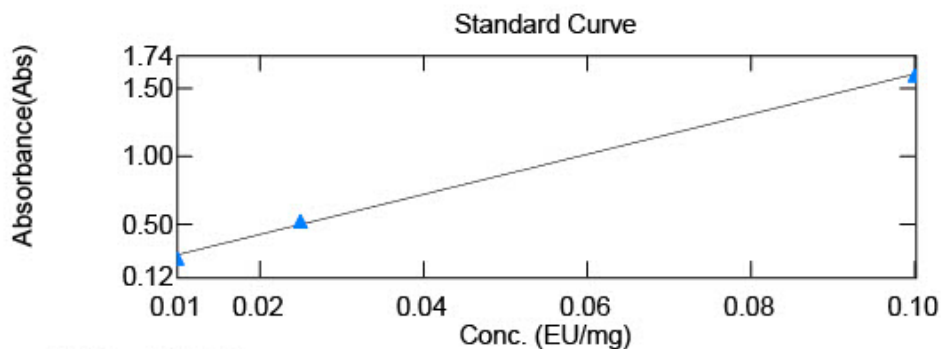


File Information

Filename: C:\UVVis-Data\Data\File_260903_204104.vqud
Date/Time: 09/03/2026 09:40:26 PM

Instrument Information

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



$$y = 14.7148x + 0.132903$$
$$r^2 = 0.99870$$

	Sample Name	Conc	Raw_WL545.0	Dilution Rate
1	LYO-0745	0.055	0.1732	20.00
2	LYO-0746	-0.026	0.1141	20.00
3	LYO-0747	2.977	1.2279	40.00
4	LYO-0748	-0.034	0.1076	20.00
5	LYO-0749	-0.042	0.1268	100.00
6	LYO-0750	-0.083	0.0716	20.00
7	LYO-0752	1.909	0.8353	40.00
8	LYO-0753	0.931	0.8176	20.00
9	LYO-0754	2.152	0.9247	40.00
10	LYO-0755	2.610	1.0929	40.00
11	LYO-0756	-0.025	0.1143	20.00
12	LYO-0757	-0.317	0.0862	100.00
13	LYO-0767	0.152	0.2445	20.00
14	LYO-0768	0.589	0.5665	20.00
15	LYO-0769	3.621	1.4649	40.00
16	LYO-0770	1.007	0.8736	20.00
17	LYO-0771	0.148	0.2419	20.00
18	LYO-0772	3.598	1.4565	40.00
19	LYO-0773	-0.045	0.0999	20.00
20	LYO-0774	3.668	1.4823	40.00

	Sample Name	Conc	Raw_WL545.0	Dilution Rate
21	LYO-0775	3.612	1.4616	40.00
22	LYO-0776	4.197	1.6769	40.00
23	LYO-0777	3.621	1.4648	40.00
24	LYO-0780	0.768	0.6977	20.00
25	LYO-0781	-0.021	0.1171	20.00
26	LYO-0782	-0.025	0.1148	20.00
27	LYO-0783	0.244	0.3121	20.00
28	LYO-0784	0.031	0.1557	20.00
29	LYO-0785	0.000	0.1329	20.00
30	LYO-086	4.729	1.0027	80.00
31	LYO-0787	3.923	1.5759	40.00
32	LYO-0788	0.099	0.2057	20.00
33	LYO-0789	1.454	1.2027	20.00
34	LYO-0790	0.264	0.3270	20.00
35	LYO-0791	1.650	0.7397	40.00
36	LYO-0792	14.164	1.4355	160.00
37	LYO-0793	-0.021	0.1176	20.00
38	LYO-0794	-0.164	0.1088	100.00

Responsibles



Mr. Ján Galbavý
CEO

Analysis results relate only to the samples tested.

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