

Certificate of Analysis

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Sample Identification

Sample Name Tesamorelin 10 mg
Batch Number CPT-TSM10-20260812-022
Date Published 2026-09-15 13:22

Results for LYO-0849

Peptides	Result	Unit	Uncertainty	Acceptable Range
Tesamorelin Assay Peptide Screening 0.1% TFA	8.51	mg	[± 0.04]	
Tesamorelin Purity Peptide Screening 0.1% TFA	98.1	%	[± 0.5]	
Tesamorelin Identification by Spectrum Peptide Screening 0.1% TFA	978		[± 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	0.012	EU/mg	[± 0]	

	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Superseded document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

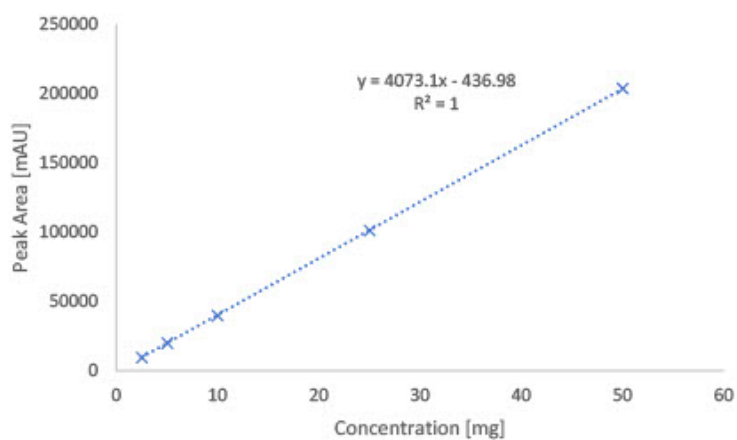
Gradient Program		
Time [min]	A [%]	B [%]
1	98	2
13.99	35	65
14	5	95
15	5	95
15.01	98	2
19	end	

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

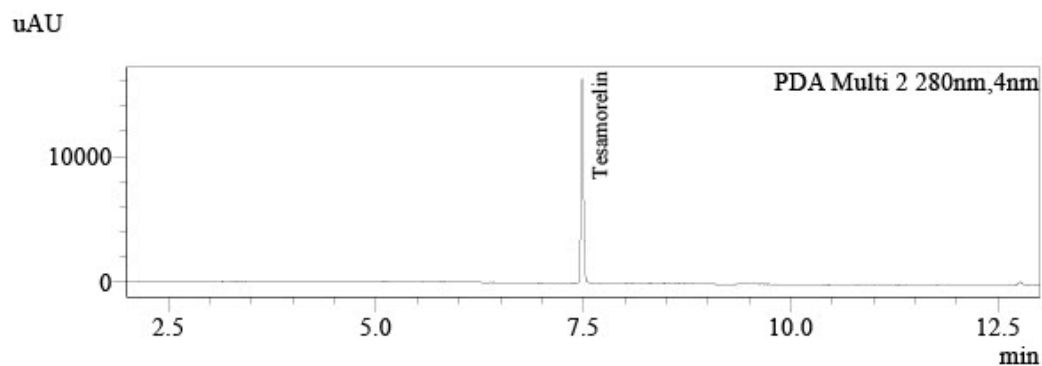
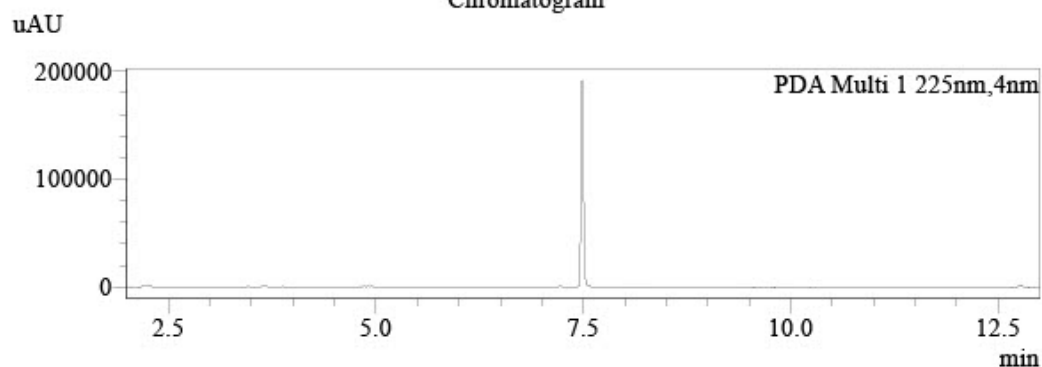


Analysis of quantity and purity of active ingredient by UHPLC with UV detection

Sample Information

Injection Volume : 2
Data File : LYO-0849__010.lcd
Method File : Peptide Screening_DFA_Group B.lcm
Date Acquired : 9/10/2026 6:57:14 PM

Chromatogram



Peak Table

PDA Ch1 225nm

Name	Ret. Time	Area	Conc.	Unit	Area%
	7.220	1743	0.000		0.421
	7.356	237	0.000		0.057
	7.485	405497	0.000		98.074
	8.221	884	0.000		0.214
	12.767	5099	0.000		1.233
		413459			100.000

Peak Table

PDA Ch2 280nm

Name	Ret. Time	Area	Conc.	Unit
Tesamorelin	7.485	34209	8.506	mg
	14.228	4086	0.000	
		38294		

Endotoxin Determination Report

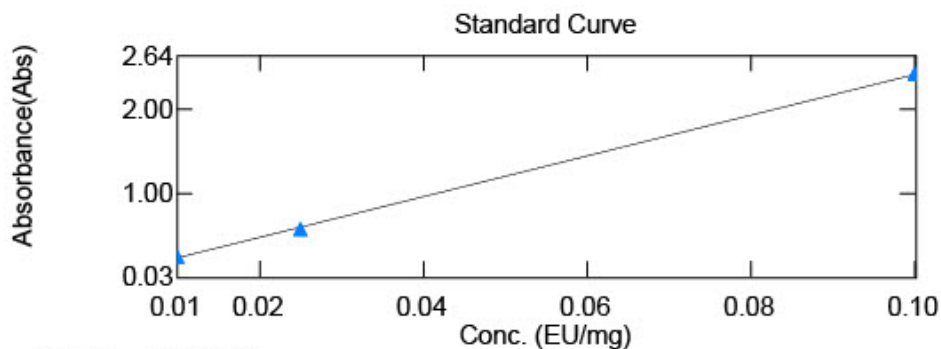


File Information

Filename: C:\UVVis-Data\Data\File_260910_110406.vqud
Date/Time: 09/10/2026 11:59:39 AM

Instrument Information

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



$$y = 24.1316x + 0.00350132$$
$$r^2 = 0.99988$$

	Sample Name	Conc	Raw_WL545.0	Dilution Rate
1	LYO-0838	0.119	0.1471	20.00
2	LYO-0839	2.461	1.4880	40.00
3	LYO-0840	0.120	0.1481	20.00
4	LYO-0841	0.123	0.1516	20.00
5	LYO-0842	0.145	0.1787	20.00
6	LYO-0843	0.119	0.1469	20.00
7	LYO-0844	0.634	0.7689	20.00
8	LYO-0845	2.332	1.4106	40.00
9	LYO-0846	0.076	0.0947	20.00
10	LYO-0847	1.766	1.0689	40.00
11	LYO-0848	0.062	0.0779	20.00
12	LYO-0849	0.081	0.1009	20.00
13	LYO-0850	2.660	1.6081	40.00
14	LYO-0851	1.122	1.3567	20.00
15	LYO-0852	0.081	0.1015	20.00
16	LYO-0853	0.657	0.7958	20.00
17	LYO-0854	0.637	0.7720	20.00
18	LYO-0855	2.207	1.3349	40.00
19	LYO-0856	0.076	0.0951	20.00
20	LYO-0857	0.080	0.1004	20.00

	Sample Name	Conc	Raw_WL545.0	Dilution Rate
21	LYO-0858	0.068	0.0853	20.00
22	LYO-0859	0.072	0.0906	20.00
23	LYO-0860	0.081	0.1008	20.00
24	LYO-0861	2.603	1.5736	40.00
25	LYO-0862	0.064	0.0813	20.00
26	LYO-0863	0.079	0.0985	20.00
27	LYO-0864	0.070	0.0877	20.00
28	LYO-0865	0.362	0.0908	100.00
29	LIQ-0068	0.007	0.1667	1.00

Responsibles



Mr. Ján Galbavý
CEO

Analysis results relate only to the samples tested.

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