

Certificate of Analysis

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Sample Identification

Sample Name Melanotan-1 10 mg
Batch Number 2210278
Date Published 2026-07-27 16:19

Results for LYO-0394

Peptides	Result	Unit	Uncertainty	Acceptable Range
Melanotan I Assay Peptide Screening 0.1% TFA	10.00	mg	[± 0.05]	
Melanotan I Purity Peptide Screening 0.1% TFA	99.8	%	[± 0.5]	
Melanotan I Identification by Spectrum (FTIR) Peptide Screening 0.1% TFA	994		[± 5]	
Melanotan I Identification by RT Peptide Screening 0.1% TFA	0.992		[± 0.005]	
Microbiology	Result	Unit	Uncertainty	Acceptable Range
Bacterial Endotoxin Chromgenic USP<85>/ Eur. Ph. 2.6.14. Bacterial Endotoxin Chromgenic Test	0.017	EU/mg	[± 0]	0 - 0.5
Mass Spectrometry	Result	Unit	Uncertainty	Acceptable Range
Molecular Ion Mass Identification (MS Deconvolution) Mass Spectrometry Identity	1646	Da	[± 1]	

	Method Specification	
Determination of identity, content and purity of Melanotan 1		
<i>Document number</i> MT1_006_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Superseded document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	0.05% TFA in Water (HPLC, Gradient Grade)
Eluent B	0.0425% 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

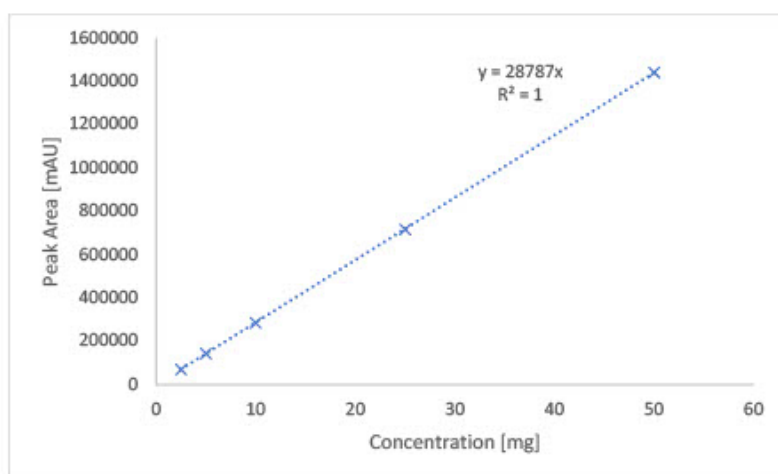
Gradient Program		
Time [min]	A [%]	B [%]
1.5	95	5
13	45	55
13.5	1	99
14.5	1	99
14.51	95	5
16	end	

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	0.0425% 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	97.5	2.5
13	45	55
13.5	1	99
14.5	1	99
14.51	97.5	2.5
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.

3. Identity Assessment

3.1 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
Column Thermostat	Shimadzu CTO-40S	L22236351602
PDA Detector	Shimadzu SPD-M40	L22276352808
SQ MS Detector	Shimadzu LCMS-2050	O12476200760

3.2 Chromatographic conditions

Chromatographic conditions	
Eluent A	0.05% TFA in Water (HPLC, Gradient Grade)
Eluent B	0.0425% TFA in Acetonitrile (HPLC, Gradient Grade)
Flow rate	0.9 mL/min
Program	Gradient elution
Injection volume	2 µL
Column Temperature	55°C
Column	Waters XSelect CSH C18, 100x2.1mm 2.5µm
Mass spectrometry	Scan: positive 280-2000 Da

Gradient Program		
Time [min]	A [%]	B [%]
1.5	97.5	2.5
13	45	55
13.5	1	99
14.5	1	99
14.51	97.5	2.5
16	end	

3.3 Molecular Ion Mass evaluation

Molecular ion mass was determined by deconvolution of multiply charged ESI-MS spectra to calculate the average neutral (zero-charge) molecular mass by equation:

$$M(\text{neutral}) = (z_i((mz_i) - H)) - ME$$

Where:

mz_i - Measured mass of charged particle

z_i - charge

H - proton mass (1.0076 Da)

ME - mass error

Analysis Report

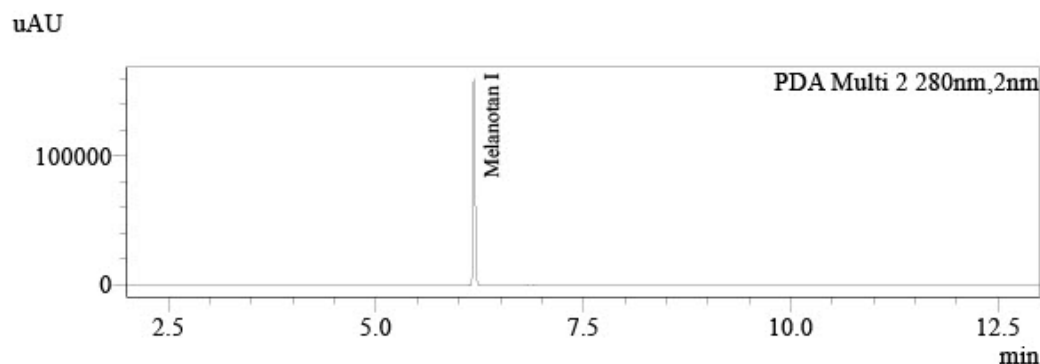
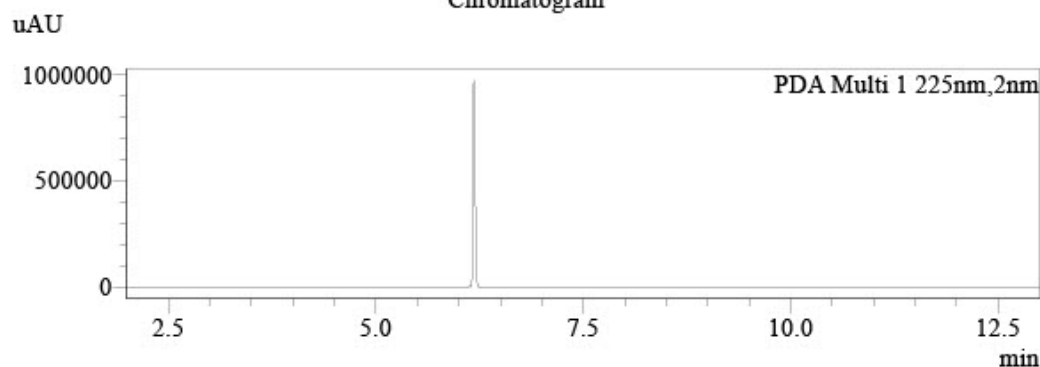


Analysis of quantity and purity of active ingredient by UHPLC with UV detection

Sample Information

Injection Volume : 2
Data File : LYO-0394__009.lcd
Method File : Peptide screening_V7_Group C.lcm
Date Acquired : 7/23/2026 5:48:34 PM

Chromatogram



Peak Table

PDA Ch1 225nm

Name	Ret. Time	Area	Conc.	Unit	Area%
	5.641	456	0.000		0.025
	5.911	711	0.000		0.040
	6.005	1085	0.000		0.060
	6.068	687	0.000		0.038
	6.181	1792031	0.000		99.775
	6.295	500	0.000		0.028
	6.552	180	0.000		0.010
	6.712	188	0.000		0.010
	6.801	240	0.000		0.013
		1796079			100.000

Peak Table

PDA Ch2 280nm

Name	Ret. Time	Area	Conc.	Unit
Melanotan I	6.181	290308	9.998	mg
		290308		

Analysis Report

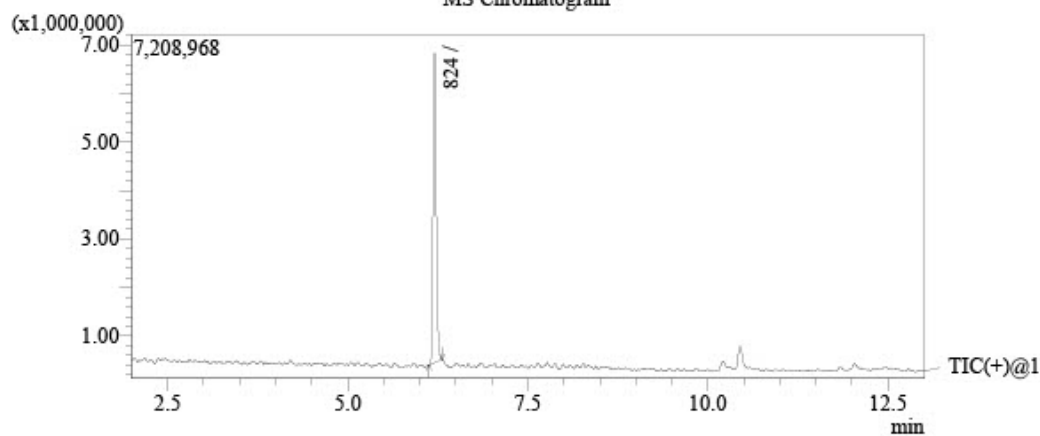


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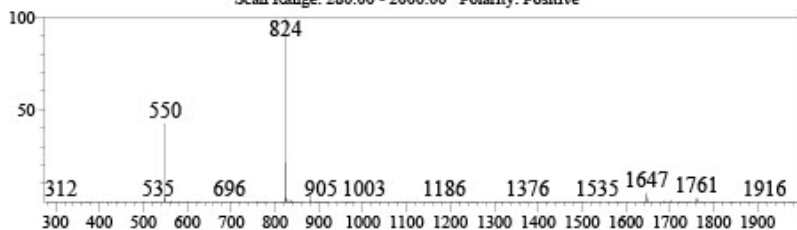
Analysis of identity of active ingredient by UHPLC with mass spectrometric detection

MS Chromatogram

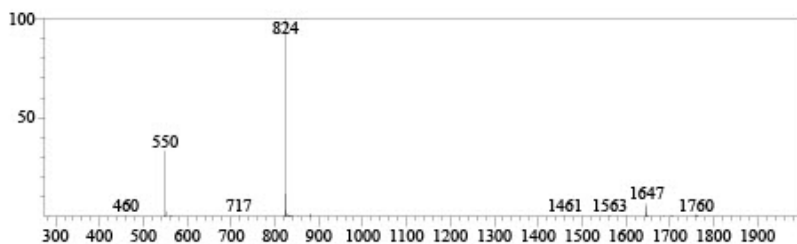


Library Search

Detected compound
Ret. Time: 6.131 Base Peak: 824
Scan Range: 280.00 - 2000.00 Polarity: Positive



Library: Peptide screening lib
Formula: C₇₈H₁₁₁N₂₁O₁₉ CAS: 75921-69-6 Mol. Weight: 1646 Ret. Index: 0
Compound Name: Melanotan 1



Endotoxin Determination Report

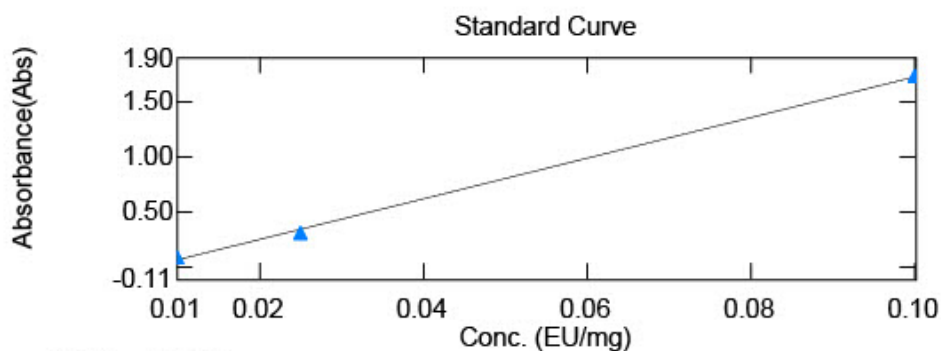


File Information

Filename: C:\UVVis-Data\Data\File_260723_122453.vqud
Date/Time: 07/23/2026 01:13:01 PM

Instrument Information

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



$$y = 18.5422x - 0.127539$$
$$r^2 = 0.99855$$

	Sample Name	Conc	Raw_WL545.0	Dilution Rate
1	LYO-0389	0.756	0.5732	20.00
2	LYO-0390	0.211	0.0677	20.00
3	LYO-0391	0.802	0.6164	20.00
4	LYO-0392	0.275	0.1271	20.00
5	LYO-0393	0.231	0.0863	20.00
6	LYO-0394	0.171	0.0309	20.00
7	LYO-0395	0.285	0.1364	20.00
8	LYO-0396	0.199	0.0569	20.00
9	LYO-0397	0.209	0.0660	20.00
10	LYO-0398	0.159	0.0201	20.00
11	LYO-0399	0.174	0.0337	20.00
12	LYO-0400	0.360	0.2067	20.00
13	LYO-0401	0.203	0.0605	20.00
14	LYO-0404	0.204	0.0613	20.00
15	LYO-0405	1.231	1.0135	20.00
16	LYO-0406	0.160	0.0206	20.00
17	LIQ-0039	0.008	0.0270	1.00

Responsibles



Mr. Ján Galbavý
CEO

Analysis results relate only to the samples tested.

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