

Certificate of Analysis

**Peptiva A brand operated by
Regenevia Pro s.r.o.**

Peptiva A brand operated by Regenevia
Pro s.r.o.
Roháčova 145/14
130 00 Prague
Czechia
support@peptiva.eu

Liquilabs s.r.o.

Inovační 122
252 41 Zlatníky-Hodkovice
Czechia
www.liquilabs.cz



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Sample Identification

Sample Name Thymosin Alpha-1 5 mg
Batch Number
Date Published 2026-07-27 09:42

Results for LYO-0364

Peptides	Result	Unit	Uncertainty	Acceptable Range
Thymosin Alpha-1 Assay Peptide Screening 0.1% TFA	6.09	mg	[± 0.03]	
Thymosin Alpha-1 Purity Peptide Screening 0.1% TFA	> 99.8	%		
Thymosin Alpha-1 Identification by Spectrum Peptide Screening 0.1% TFA	980		[± 5]	
Thymosin Alpha-1 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	> 0.5	EU/mg	[± 0.01]	0 - 0.5 ▲ Out of specification
Mass Spectrometry	Result	Unit	Uncertainty	Acceptable Range
Molecular Ion Mass Identification (MS Deconvolution) Mass Spectrometry Identity	3108	Da	[± 1]	

	Method Specification	
Determination of identity, content and purity of Thymosin Alpha-1		
<i>Document number</i> THYMA_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Superseded document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	225nm

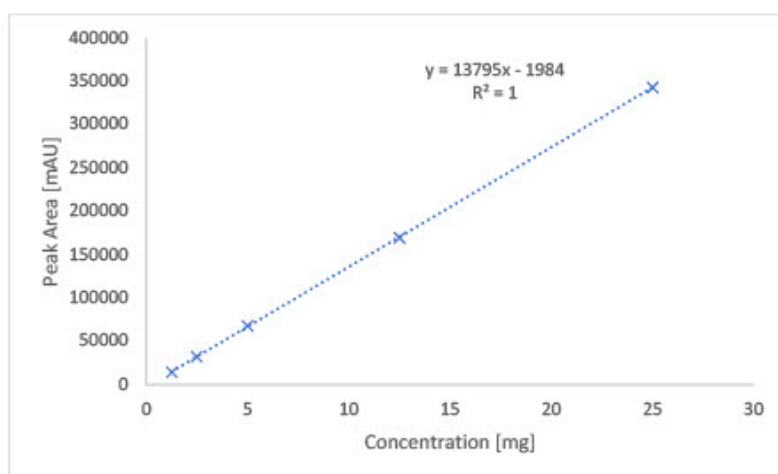
Gradient Program		
Time [min]	A [%]	B [%]
1.5	95	5
13	45	55
13.5	1	99
14.5	1	99
14.51	95	5
16	end	

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	0.0425% 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 225 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
Colum 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
Colum 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



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Analytical services

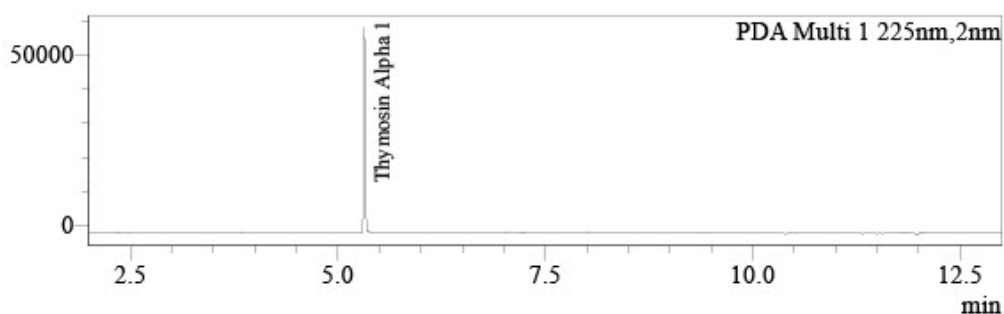
Analysis of quantity and purity of active ingredient by UHPLC with UV detection

Sample Information

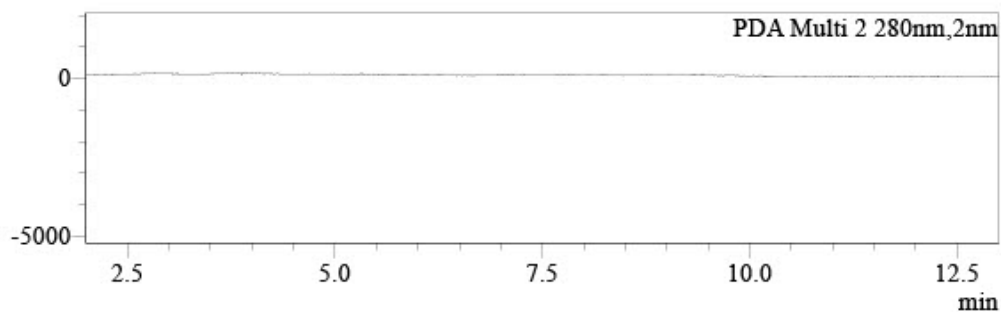
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Data File : LYO-0364__004.lcd
Method File : Peptide screening_V7_Group C.lcm
Date Acquired : 7/20/2026 4:05:20 PM

Chromatogram

uAU



uAU



Peak Table

PDA Ch1 225nm

Name	Ret. Time	Area	Conc.	Unit	Area%
Thymosin Alpha 1	5.319	82042	6.091	mg	99.824
	5.373	65	0.000		0.079
	5.429	79	0.000		0.096
		82186			100.000

Peak Table

PDA Ch2 280nm

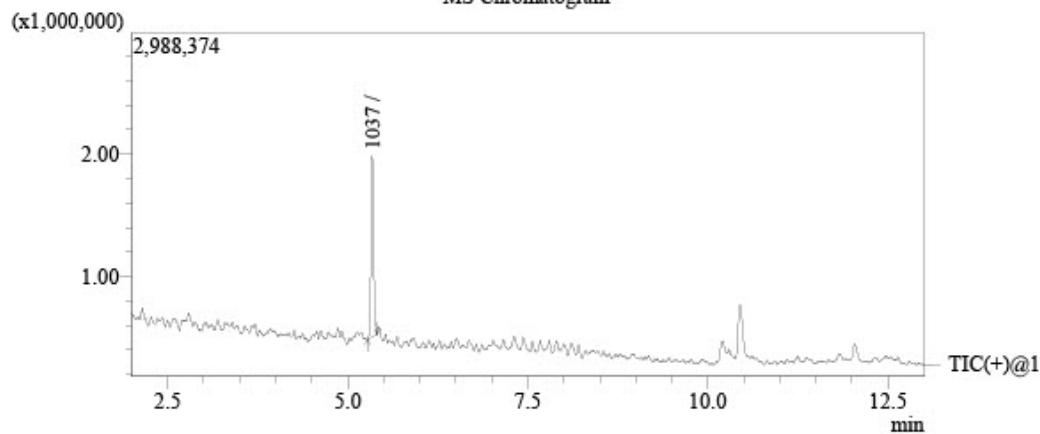
Name	Ret. Time	Area	Conc.	Unit

Analysis Report



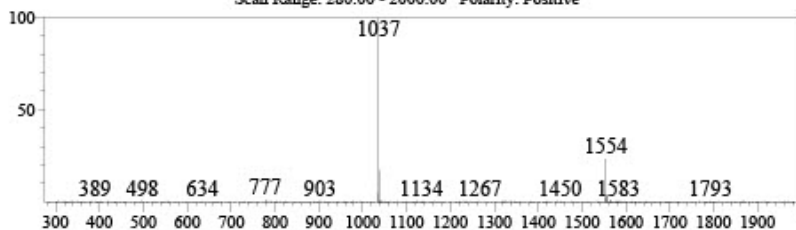
Analysis of identity of active ingredient by UHPLC with mass spectrometric detection

MS Chromatogram

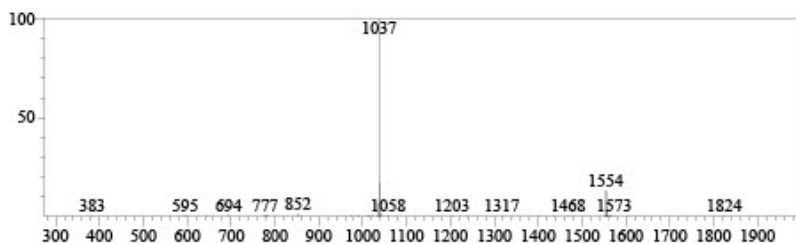


Library Search

Detected compound
Ret.Time: 5.279 Base Peak: 1037
Scan Range: 280.00 - 2000.00 Polarity: Positive



Library: Peptide screening lib
Formula: C₁₂₉H₂₁₅N₃₃O₅₅ CAS: 62304-98-7 Mol.Weight: 3108 Ret.Index: 0
Compound Name: Thymosin Alpha 1



Endotoxin Determination Report

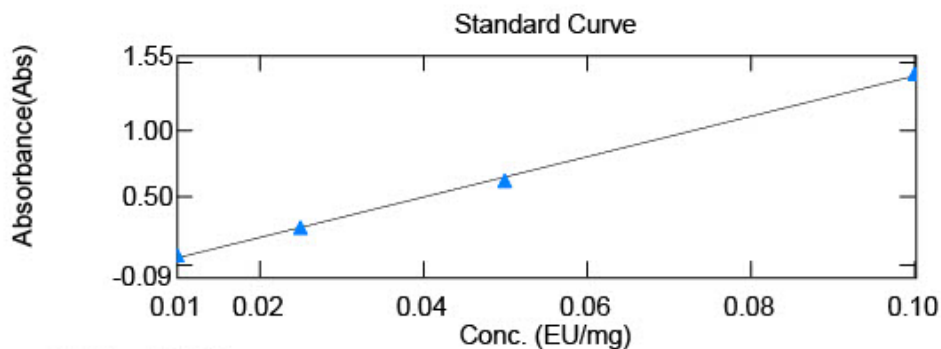


File Information

Filename: C:\UVVis-Data\Data\File_260720_124259.vqud
Date/Time: 07/20/2026 12:42:33 PM

Instrument Information

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



$$y = 15.0474x - 0.104044$$
$$r^2 = 0.99891$$

	Sample Name	Conc	Result	Dilution Rate
1	LYO-0363	0.267	0.097	20.00
2	LYO-0364	3.062	2.199	20.00
3	LYO-0365	2.603	1.855	20.00
4	LYO-0366	0.702	0.424	20.00
5	LYO-0367	3.216	2.315	20.00
6	LYO-0368	0.487	0.263	20.00
7	LYO-0369	0.422	0.213	20.00
8	LYO-0371	0.226	0.066	20.00
9	LYO-0372	0.243	0.079	20.00
10	LYO-0373	0.422	0.023	50.00
11	LYO-0374	0.303	0.124	20.00
12	LYO-0375	3.200	2.304	20.00
13	LYO-0376	0.664	0.395	20.00
14	LIQ-0037	0.101	0.048	10.00
15	LYO-0378	1.528	1.045	20.00

Responsibles



Mr. Ján Galbavý
CEO

Analysis results relate only to the samples tested.

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