

Certificate of Analysis

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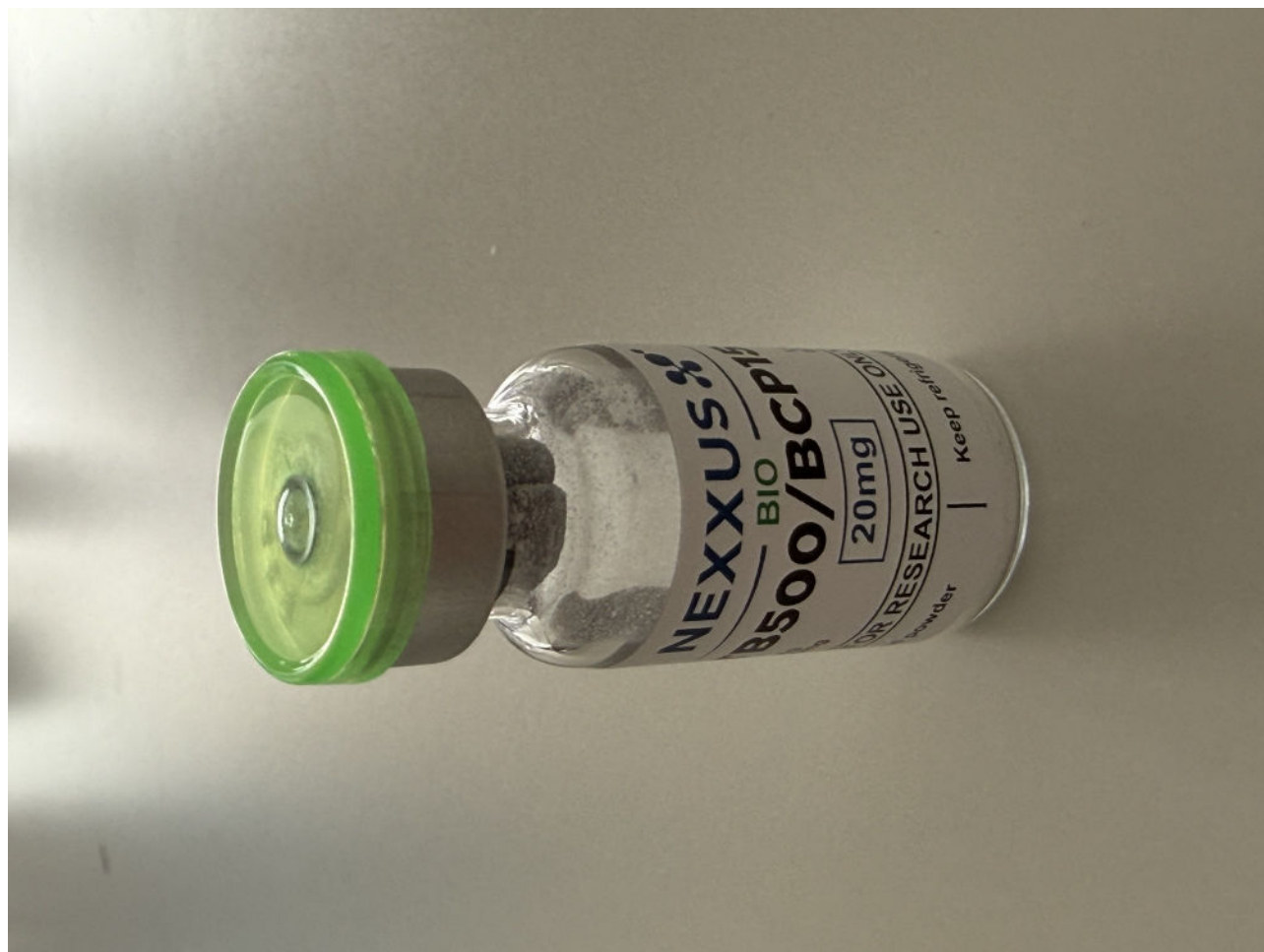
[Verify Results Online](#)

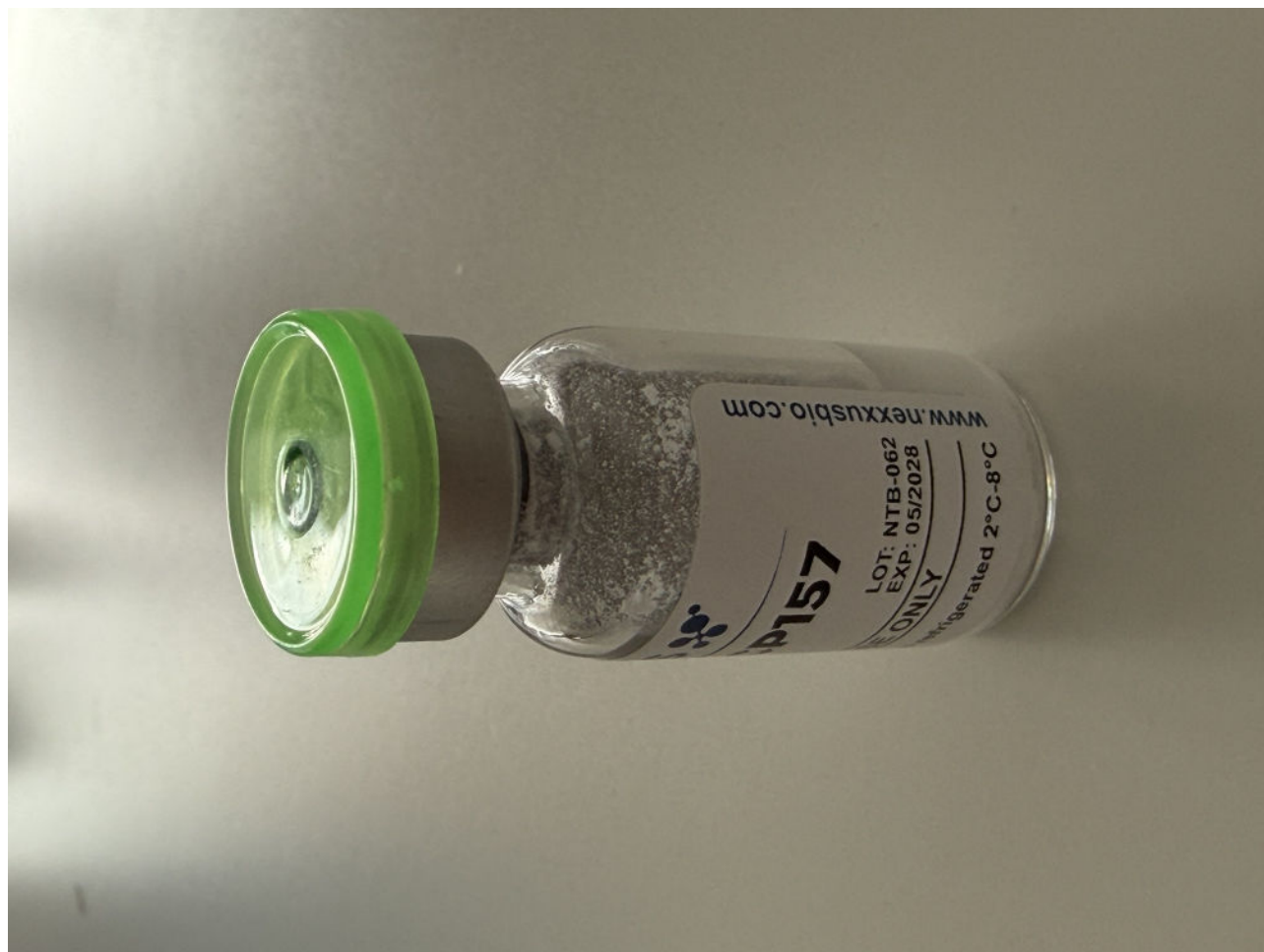
Sample Identification

Sample Name TB500 + BPC-157 20 mg
Batch Number NTB-062
Date Published 2026-08-27 13:25

Results for LYO-0692

Peptides	Result	Unit	Uncertainty	Acceptable Range
BPC-157 Assay Peptide Screening 0.1% TFA	11.78	mg	[± 0.06]	
BPC-157 Purity Peptide Screening 0.1% TFA	99.6	%	[± 0.5]	
BPC-157 Identification by RT Peptide Screening 0.1% TFA	0.993		[± 0.005]	
Thymosin Beta 4 (TB-500) Assay Peptide Screening 0.1% TFA	11.52	mg	[± 0.06]	
Thymosin Beta 4 (TB-500) Purity Peptide Screening 0.1% TFA	> 99.8	%		
Thymosin Beta 4 (TB-500) Identification by RT Peptide Screening 0.1% TFA	0.995		[± 0.005]	
Microbiology	Result	Unit	Uncertainty	Acceptable Range
Bacterial Endotoxin Chromgenic USP<85>/ Eur. Ph. 2.6.14. Bacterial Endotoxin Chromgenic Test	0.002	EU/g	[± 0]	(RT)
Elemental Impurities	Result	Unit	Uncertainty	Acceptable Range
Arsenic Elemental Impurities screening USP (232) / Ph. Eur. 5.20 / 2.4.20	< 0.001	ppm		
Cadmium Elemental Impurities screening USP (232) / Ph. Eur. 5.20 / 2.4.20	< 0.001	ppm		
Quicksilver Elemental Impurities screening USP (232) / Ph. Eur. 5.20 / 2.4.20	< 0.001	ppm		
Lead Elemental Impurities screening USP (232) / Ph. Eur. 5.20 / 2.4.20	< 0.001	ppm		
Mass Spectrometry	Result	Unit	Uncertainty	Acceptable Range
Molecular Ion Mass Identification (BPC-157) Mass Spectrometry Identity	1419	Da	[± 1]	
Molecular Ion Mass Identification (TB-500) Mass Spectrometry Identity	4963	Da	[± 1]	





	Method Specification		
Determination of identity, content and purity of BPC-157			
<i>Document number</i> BPC_008_2026	<i>Superseded document</i> -	<i>Number of pages</i> 4	

1. Content Assesment

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	225nm

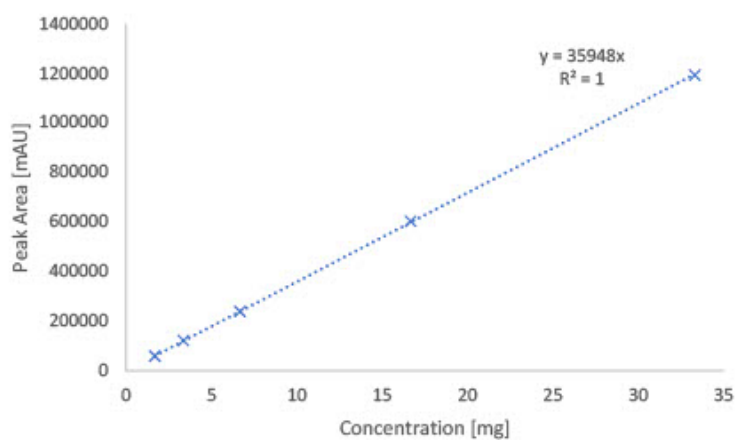
Gradient Program		
Time [min]	A [%]	B [%]
1	98	2
13.99	35	65
14	5	95
15	5	95
15.01	98	2
19	end	

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
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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.

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
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Program	Gradient elution
Injection volume	2 µL
Column Temperature	60°C
Column	Waters XSelect CSH C18, 100x2.1mm 2.5µm
Detection	MS 220-2000 Da

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	

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

	Method Specification	
Determination of identity, content and purity of Thymosin Beta 4		
<i>Document number</i> TB4_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
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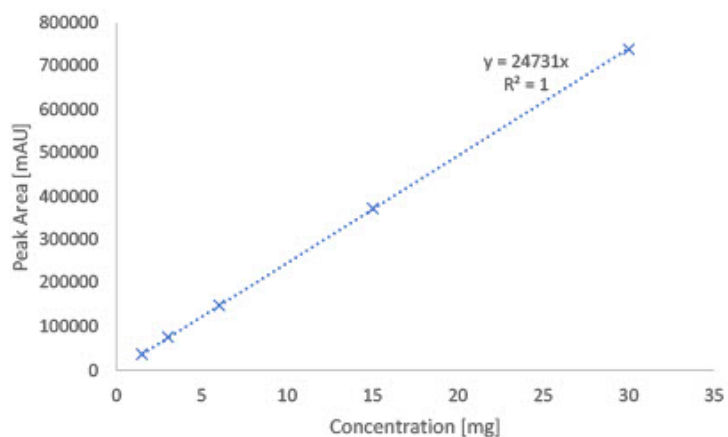
Gradient Program		
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1.4. Calibration curve

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

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3. Identity Assessment

3.1 Instrumentation

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Gradient Program		
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15	5	95
15.01	98	2
19	end	

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

Where:

mz_i - Measured mass of charged particle

z_i - charge

H - proton mass (1.0076 Da)

ME - mass error

Analysis Report



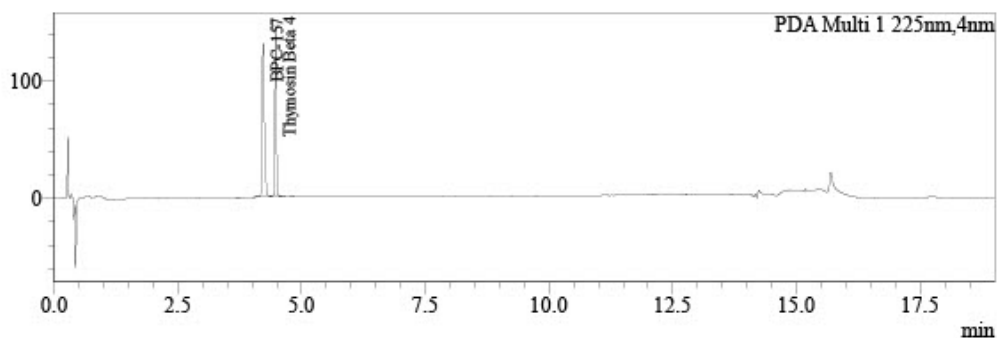
Analysis of quantity of active ingredient by UHPLC with MS detection

Sample Information

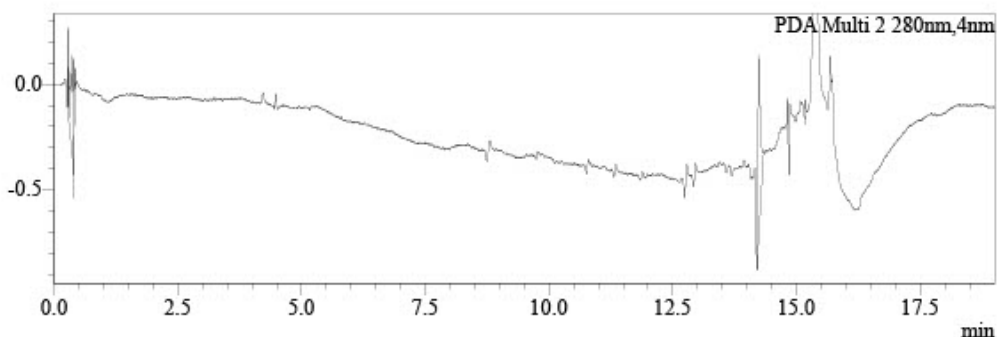
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Method File : Peptide Screening_DFA_Group C.lcm
Date Acquired : 8/20/2026 7:28:11 PM

Chromatogram

mAU



mAU



Peak Table

PDA Ch1 225nm

Peak#	Name	Ret. Time	Area	Area%	Conc.	Unit
1		3.724	331	0.046	0.000	
2		4.058	1334	0.187	0.000	
3	BPC-157	4.222	424890	59.587	11.782	mg
4		4.394	262	0.037	0.000	
5	Thymosin Beta 4	4.476	285979	40.106	11.517	mg
6		4.567	-117	-0.016	0.000	
7		4.812	382	0.054	0.000	
Total			713062	100.000		

Peak Table

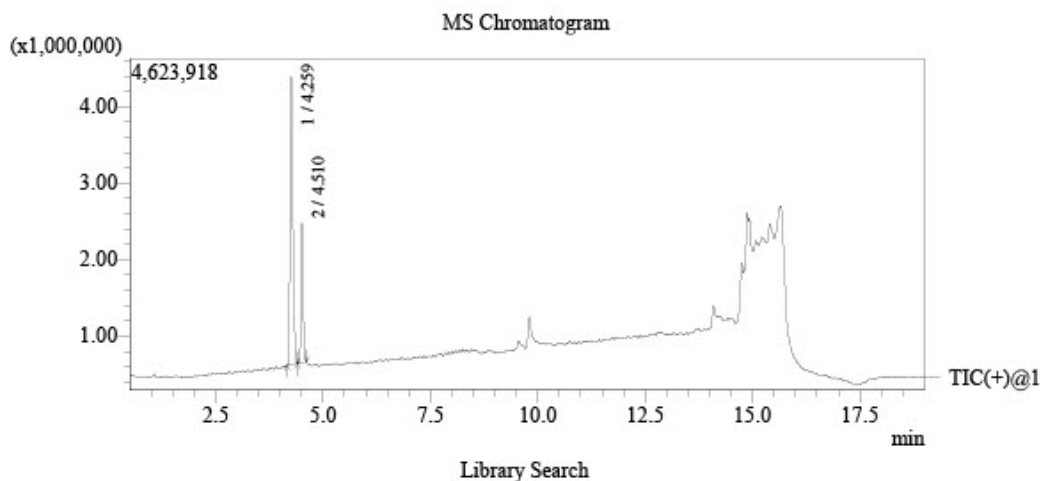
PDA Ch2 280nm

Peak#	Name	Ret. Time	Area	Area%	Conc.	Unit
1		0.280	2114	42.386	0.000	
2		14.242	2873	57.614	0.000	
Total			4987	100.000		

Analysis Report

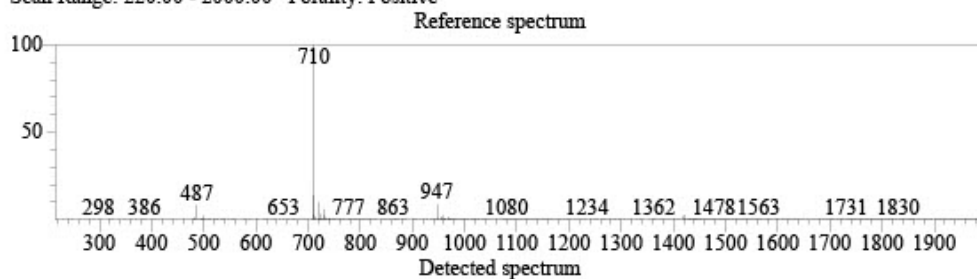


Identification of active ingredient by UHPLC Mass Spectrometry



Base Peak: 710(1808635)

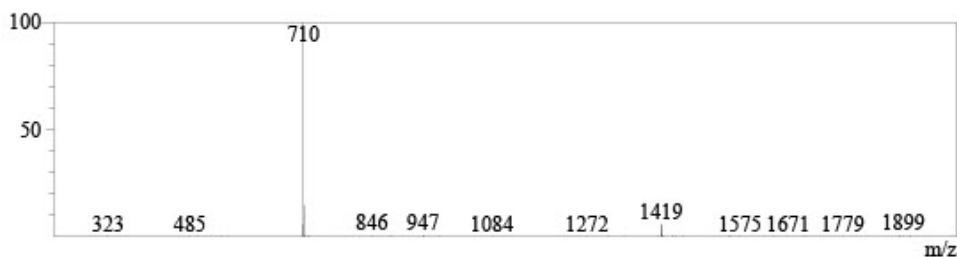
Scan Range: 220.00 - 2000.00 Polarity: Positive



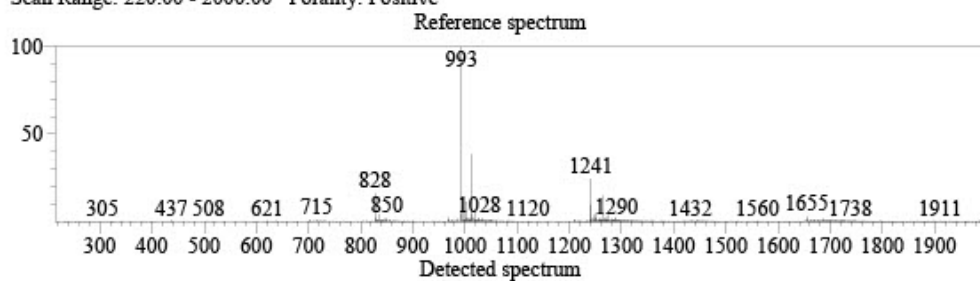
Library: Peptide screening.lib

Formula: C₆₂H₉₈N₁₆O₂₂ CAS: 137525-51-0 Mol.Weight: 1418(0!=)

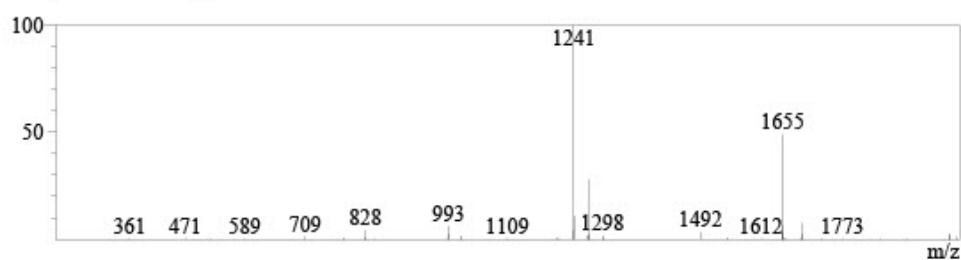
Compound Name: BPC-157



Base Peak: 993(460167)
Scan Range: 220.00 - 2000.00 Polarity: Positive



Library: Peptide screening.lib
Formula: C₂₁₂H₃₅₀N₅₆O₇₈S CAS: 77591-33-4 Mol.Weight: 4963(0!=)
Compound Name: Thymosin Beta 4



Endotoxin Determination Report

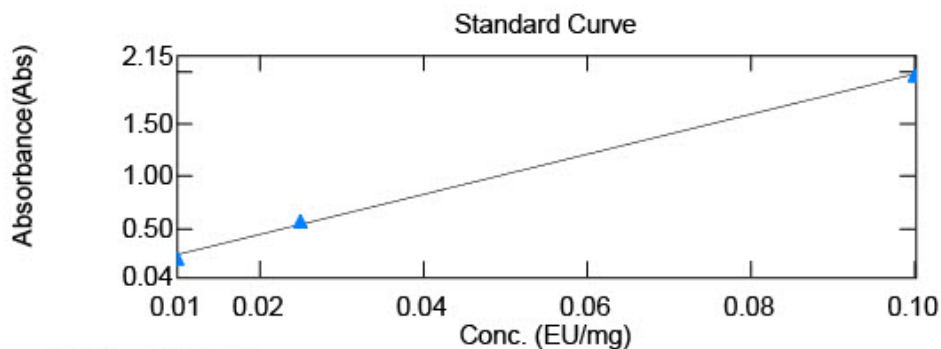


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Instrument Information

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



$$y = 19.2242x + 0.0569806$$
$$r^2 = 0.99866$$

	Sample Name	Conc	Raw_WL545.0	Dilution Rate
1	LIQ-0055	0.003	0.1086	1.00
2	LIQ-0056	0.734	1.4685	10.00
3	LYO-0620	5.092	1.0358	100.00
4	LYO-0621	0.032	0.0880	20.00
5	LYO-0622	0.906	0.9279	20.00
6	LYO-0623	0.057	0.1122	20.00
7	LYO0624	2.521	1.2687	40.00
8	LYO-0625	0.073	0.1270	20.00
9	LYO-0692	0.043	0.0981	20.00
10	LYO-0627	0.394	0.4356	20.00
11	LYO-0628	0.051	0.1056	20.00
12	LIQ-0065	0.056	0.1113	20.00
13	LYO-0629	2.182	1.1055	40.00
14	LYO-0630	0.053	0.1084	20.00
15	LYO-0631	1.632	0.8411	40.00
16	LYO-0645	1.560	0.8067	40.00
17	LYO-0646	0.058	0.1130	20.00
18	LYO-0647	0.155	0.2056	20.00
19	LYO0648	2.452	1.2354	40.00
20	LYO-0649	1.360	0.7105	40.00

	Sample Name	Conc	Raw_WL545.0	Dilution Rate
21	LYO-0650	0.043	0.0986	20.00
22	LYO-0651	2.908	1.4546	40.00
23	LYO-0652	0.129	0.1805	20.00
24	LYO-0653	0.156	0.0870	100.00

Responsibles



Mr. Ján Galbavý
CEO

Analysis results relate only to the samples tested.

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