

ANALYTICAL CERTIFICATE

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Sample name	Thymosin Alfa 1
Batch No.	2023165
Sample No.	01
Specification	NA
Manufacturing date	NA

1. Peptide content by HPLC/CLND:

1.1 HPLC Instrument:

Pump: Agilent 1200 Series, Quat Pump G1311A
Sampler: Agilent 1260 Series, Hip ALS G1367E
Degasser: Agilent 1200 Series, Degasser G1379B
Detectors: Agilent 1200 Series, VWD G1314B
Nitrogen detector Antek 8060

1.2 HPLC conditions:

Eluents: A – MilliQ water
B – isopropanol
D – 1% TFA in MilliQ water
Flow rate: 1 mL/min
Gradient:

Time	A (%)	B (%)	D (%)
0	90	0	10
1	90	0	10
9	10	80	10
10	10	80	10
11	90	0	10
15	90	0	10

Column: ARION 5 μ C4-BIO 300 A, 4.6 x 100 mm
Serial No 221258

1.3 Sample preparation:

The whole amount of Thymosin Alfa 1 (5 mg) was dissolved in 1 mL of water:MeCN (70:30, pH 8.0).

Injection: 1 μ L

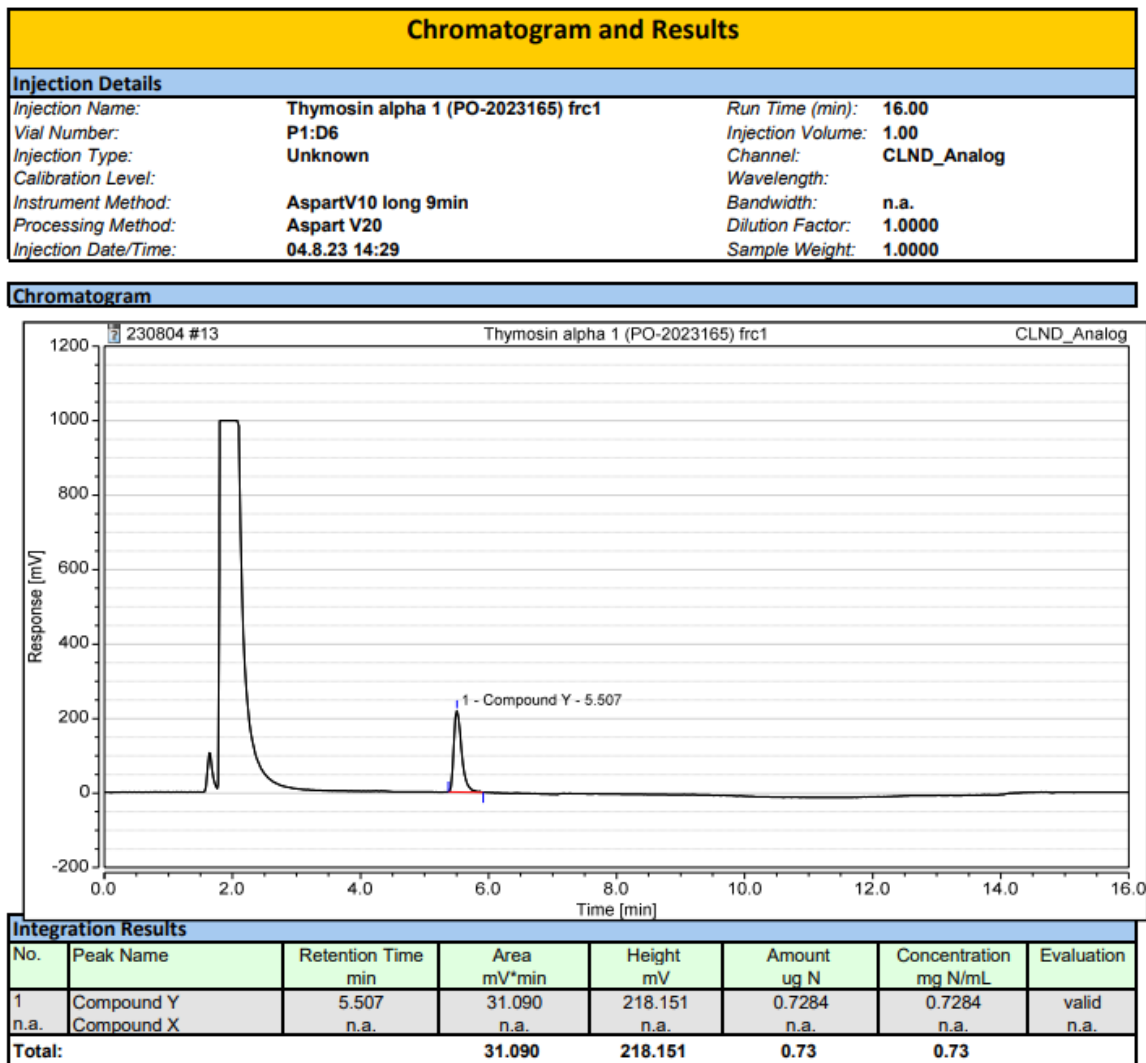
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1.4 Chromatograms and calibration curve:

Instrument:CLND-2 Sequence:230804

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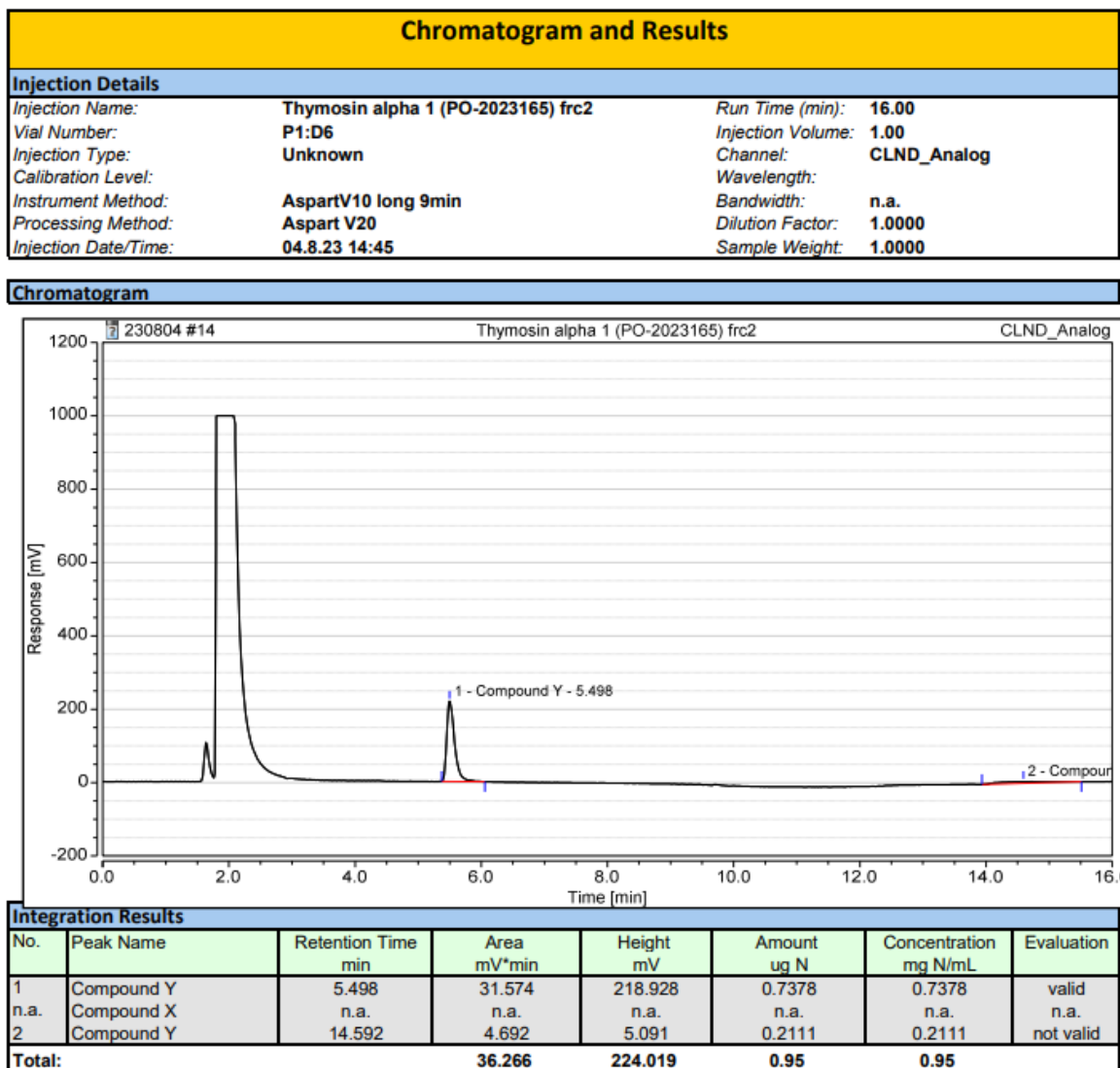


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Instrument:CLND-2 Sequence:230804

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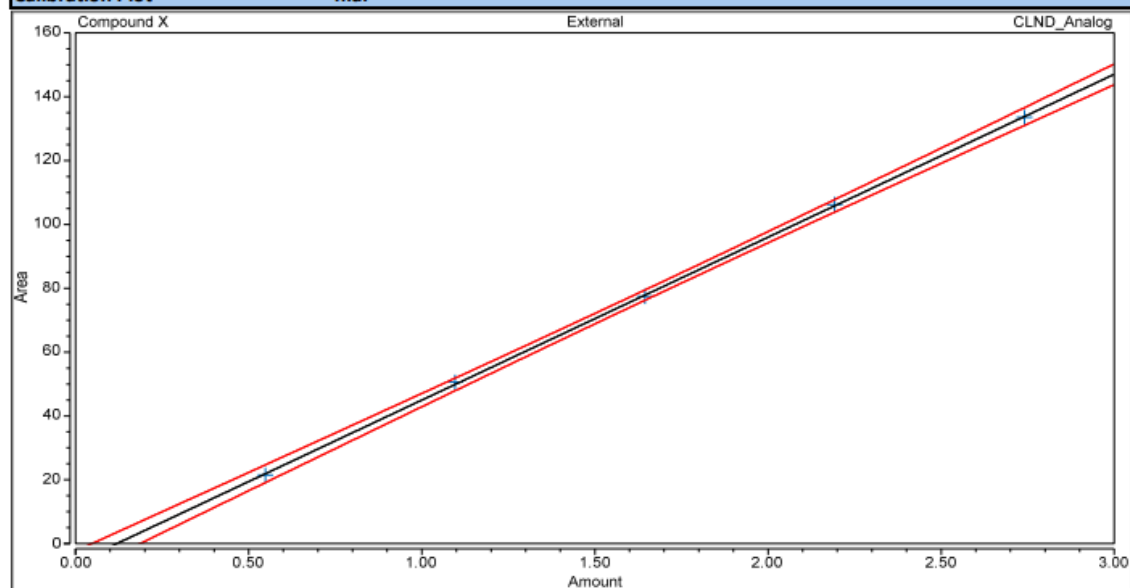
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Instrument: CLND-2 Sequence: 230804

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Calibration			
Calibration Details		n.a.	
Calibration Type	Lin, WithOffset	Offset (C0)	n.a.
Evaluation Type	Area	Slope (C1)	n.a.
Number of Calibration Points	n.a.	Curve (C2)	n.a.
Number of disabled Calibration Points	n.a.	R-Square	n.a.

Calibration Plot	n.a.
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Calibration Results		n.a.					
No.	Injection Name	Calibration Level	X Value	Y Value	Y Value	Area mV*min	Height mV
			CLND_Analog Compound X	CLND_Analog Compound X	CLND_Analog Compound X	CLND_Analog Compound X	CLND_Analog Compound X
2	Aspart5	1	2.7408	133.5080	133.5080	133.508	833.663
3	Aspart4	1	2.1926	106.2189	106.2189	106.219	672.462
4	Aspart3	1	1.6445	77.4350	77.4350	77.435	480.536
5	Aspart2	1	1.0963	50.5943	50.5943	50.594	318.096
6	Aspart1	1	0.5482	21.4499	21.4499	21.450	136.941

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1.4 Results:

NNC: Thymosin Alpha 1 (PO-;		Salt:	0
MW (calculated) g/mol	N content (calculated) %	N conc. (measured) mg × N/ml	
3108,32	14,87	0,7331	
Theoretical Volume ml		Lyophilizate amount mg	
1,00		5,00	
Peptide concentration mg/ml nmol/ml		Quantified amount mg nmol	
4,93 1586		4,9 1 586	
Peptide content assay %			
98,6			

Summary table:

Peptide	Aliquoting (mg)	Total weight of sample (mg)	Content of the peptide by CLND (mg)	Content of the peptide in the sample (%)	Content of the peptide against the amount on label.
Thymosin Alfa 1	5	NA	4.93	NA	98,6%

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2. Purity assessment by UPLC:

2.1 HPLC Instrument:

LC-System Waters Acquity UPLC
Detectors: UV or DAD at 214 nm

2.2 HPLC conditions:

Eluents: A – MilliQ water + 0.05% TFA
 B – acetonitrile + 0.05% TFA
Flow rate: 0.40 mL/min
Gradient: from 5% B to 60% B in 4 min, according to chromatogram results
Column: Waters Acquity BEH, C-18, 1.7µm, 2.1mm x 50mm
 Part No 186002353

2.3 Sample preparation:

The whole amount of Thymosin Alfa 1 (5 mg) was dissolved in 1 mL of water:MeCN (70:30, pH 8.0).

Injection: 0,2 µL

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2.4 Chromatogram of Thymosin Alfa 1 (PO-20223165)

Sample information

UPLC2

Channel Description ACQUITY TUV ChA 214nm

Vial : 1:B,6 Vol. : 0.20 ul

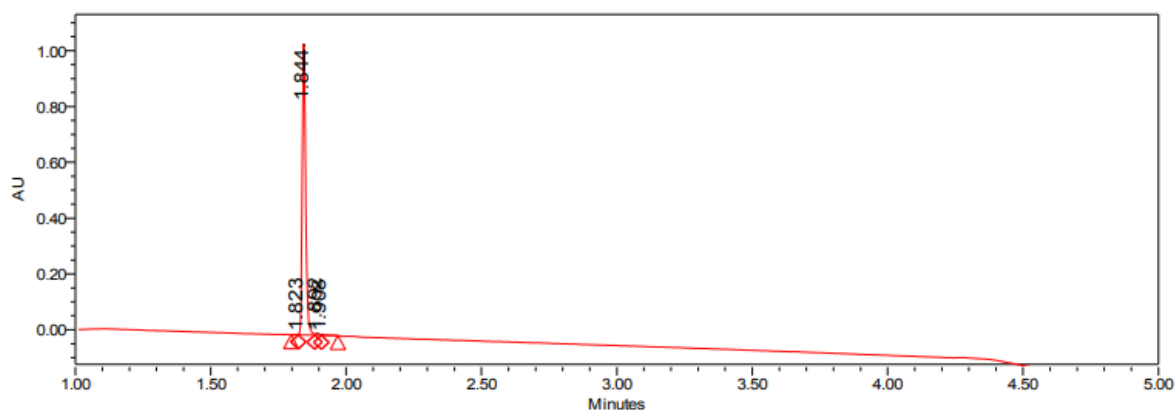
Sample: Thymosin alpha 1 (PO-2023165)

Date Acquired 8/4/2023 2:31:31 PM CEST

Date Processed 8/4/2023 2:51:00 PM CEST

Acq Method Set :

Gr_5_60_4mi_40C_0_45_K2_met_s



	RT	Area	Height (μV)	% Area
1	1.823	1470	2106	0.16
2	1.844	926786	1043667	98.44
3	1.892	7530	6509	0.80
4	1.908	5648	3231	0.60

A: 0.05% TFA in water

B: 0.05% TFA in acetonitrile

Gradient :

0.0 - 0.5min 5 - 5 % B

0.5 - 4 min 5 - 60 % B

4.0 - 4.5 min 60 - 100 % B

4.5 - 5.0min 100 % B

5.0 - 5.5min 100 - 5 % B

6min 5 % B

0.45ml/min

Acquity UPLC BEHC18, 1.7um, 2.1 x 50 mm column

column oven temp. = 40 °C

2.5 Result of purity assessment

The overall purity is 98.44 % at 214 nm.

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CONCLUSION:

The sample Thymosin Alfa 1 (Batch No. 2023165) was analyzed for peptide content and UV purity.

Peptide content is 98.6 % (4.93 mg in 5 mg)

Purity is 98.44 % (UPLC at 214 nm).

ANALYSIS COMPLETED:	Date: 04.08.2023
Issued by QC:	Date: 09.08.2023 Signature: 

Analytical report AR-24-KT-043642-02



Testing laboratory:

Eurofins Environment Testing Slovakia s.r.o.
 Robotnícka 820/36, 039 01 Turčianske Teplice
 IČO: 53 248 376
 Place of work:
Accredited testing laboratory Turčianske Teplice
 Robotnícka 820/36, 039 01 Turčianske Teplice
 tel: 043/490 1562
 RegistrationEnviroSK@etcee.eurofins.com, www.eurofins.sk

Customer:

PARTICLE s.r.o.
 Kolonáda 4490/18
 984 01 Lučenec
 SLOVAKIA

Date of Sample Receipt: 22.11.2024 Date of Testing: 22.11.2024 - 26.11.2024

Issue date: 03.12.2024

Information about Sampling:

Sampler: customer

Sample information: 104-2024-00048109

Sample description: Thymosin alpha 1 (PO-2023165)

Material: Peptidy

Physical and chemical tests

Parameter	Unit	Allowed Value	Measured Value	Uncertainty of Method measurement*	Testing method	E	SL	TT
Arsenic (As)	mg/kg	-	<1,5	-	ICP-MS	LS-PP-CH-85	-	TR A
Cadmium (Cd)	mg/kg	-	<0,2	-	ICP-MS	LS-PP-CH-85	-	TR A
Lead (Pb)	mg/kg	-	<0,5	-	ICP-MS	LS-PP-CH-85	-	TR A
Mercury (Hg)	mg/kg	-	<0,3	-	ICP-MS	LS-PP-CH-85	-	TR A

Notes:

E - evaluation
 S - satisfied
 NS - not satisfied
 (A) - accredited sampling
 (SA) - accredited sampling executed under the subcontract
 ŠPP - Standard operation procedure
 ND - not detected by given method
 LOQ, LQ – limit of quantification
 CFU - Colony forming unit
 NM - necessary quantity
 m - the highest allowed value at the case of one sample
 M, c - "M" highest allowed value for the number "c" at the case of 5 sample`s evaluation
 * - measurement uncertainty – sampling and analysis – determined by extension coefficient k=2 (with probability of 95%). If sample is taken by the customer uncertainty of sampling is not available.
 - uncertainty given in % reflects the uncertainty from the result of measurement.
 ** - Acceptable to consumers and no abnormal change
 SL - analysis laboratory: NZ-Nové Zámky, TR-Turčianske Teplice, RK-Ružomberok, TV-Trebišov

Disclaimer:

Laboratory is a disclaimer when the information is supplied by the customer (#) and can affect the validity of results. If the sample has been provided by the customer, the results refer to the sample as it was received. Gauges and measuring equipment used for testing were calibrated or attested in accordance with the valid metrological instructions. The above mentioned test results refer to the tested sample only! The result given in this Analytical report and marked as non accredited test shall not be a subject of accreditation. The result given in this Analytical report and marked as sub- delivery is the result of a Subcontractors gauging made under the terms and conditions of a contract concluded with him. This Analytical report shall not be reproduced except in full colour version, without written approval of the laboratory. SNAS is a Signatory to the Multilateral Agreement MRA ILAC.

Responsible for correctness:

Michaela Ruttkayová
Specialist worker

Worked out by: Andrea Podušelová

Validity check of document

**Test Certificate approved by**Michaela Ruttkayová
Specialist worker