

ANALYTICAL CERTIFICATE

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Sample name	CJC-1295+DAC
Batch No.	2023146
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 CJC-1295+DAC (2 mg) was dissolved in 1 mL of DMSO.
Injection: 5.0 μ L

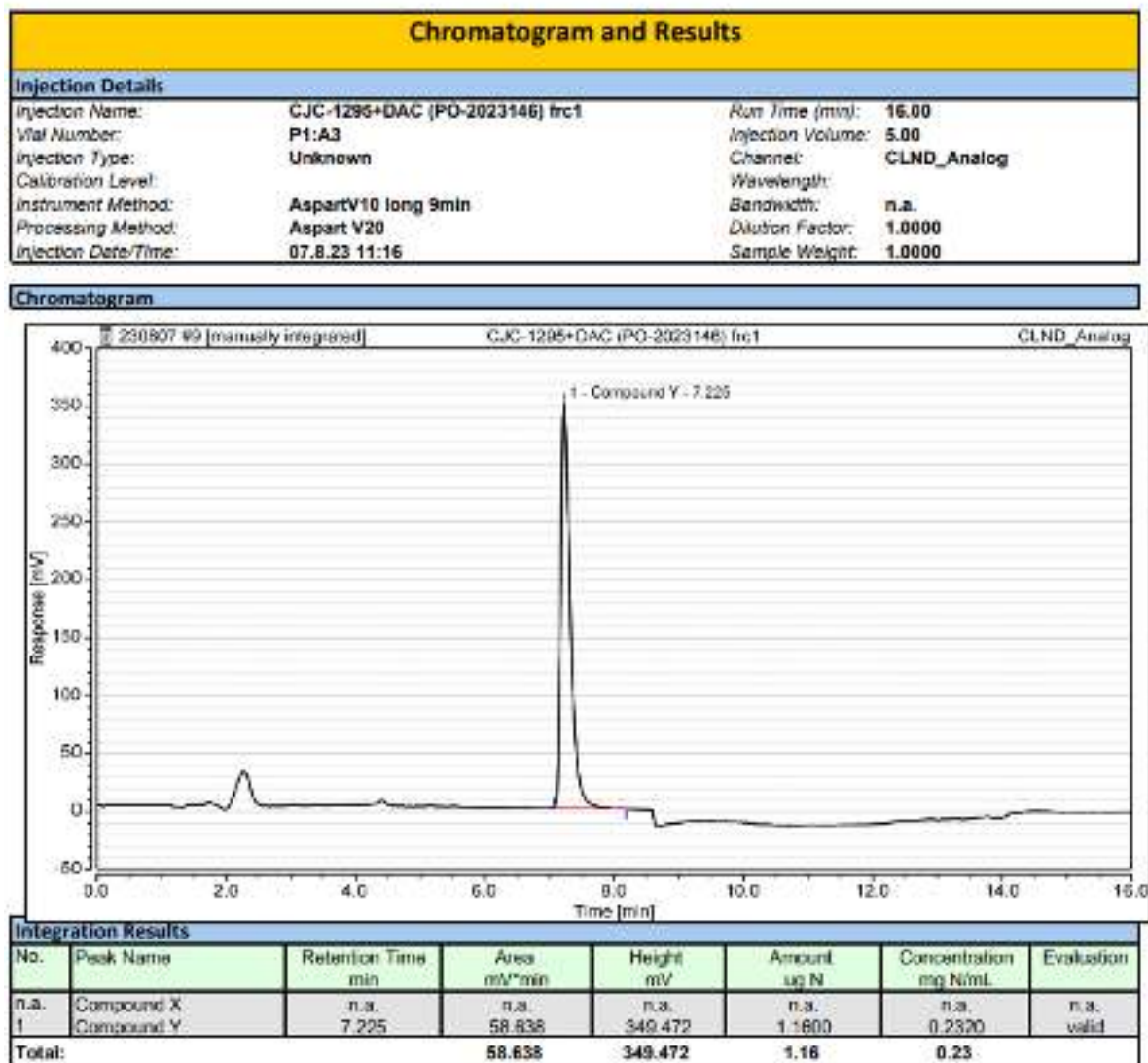
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1.4 Chromatograms and calibration curve:

Instrument: CLND-2 Sequence: 230607

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Instrument: CLND-2 Sequence: 230807

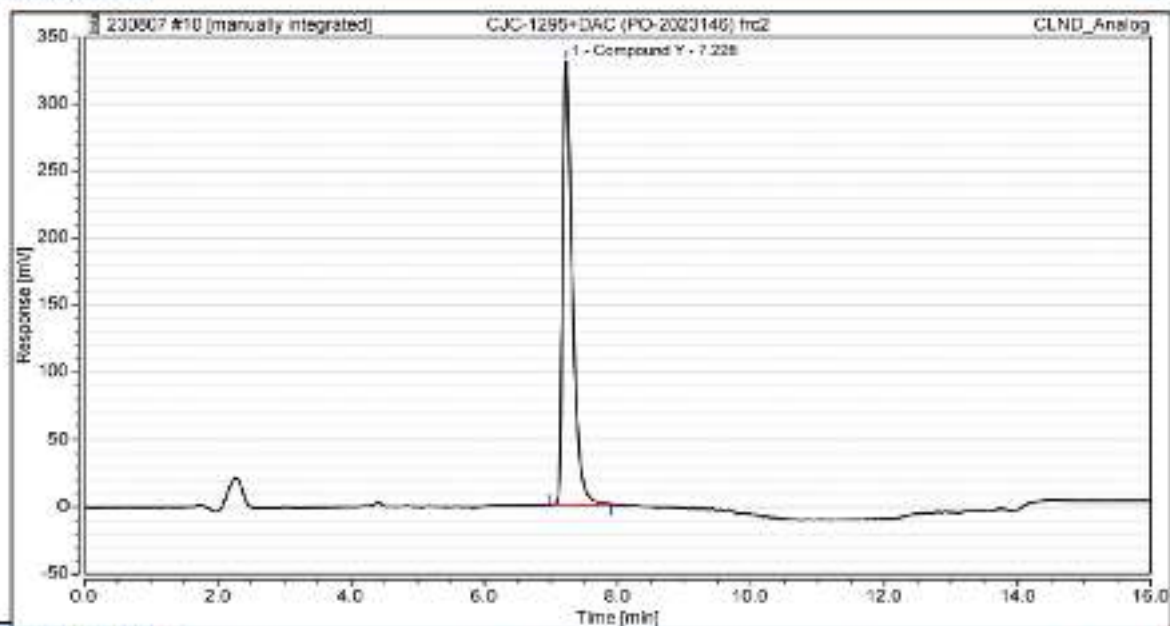
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Chromatogram and Results

Injection Details

Injection Name:	CJC-1295+DAC (PO-2023146) frc2	Run Time (min):	16.00
Vial Number:	P1:A3	Injection Volume:	5.00
Injection Type:	Unknown	Channel:	CLND_Analog
Calibration Level:		Wavelength:	
Instrument Method:	AspartV10 long 9min	Bandwidth:	n.a.
Processing Method:	Aspart V20	Dilution Factor:	1.0000
Injection Date/Time:	07.8.23 11:33	Sample Weight:	1.0000

Chromatogram



Integration Results

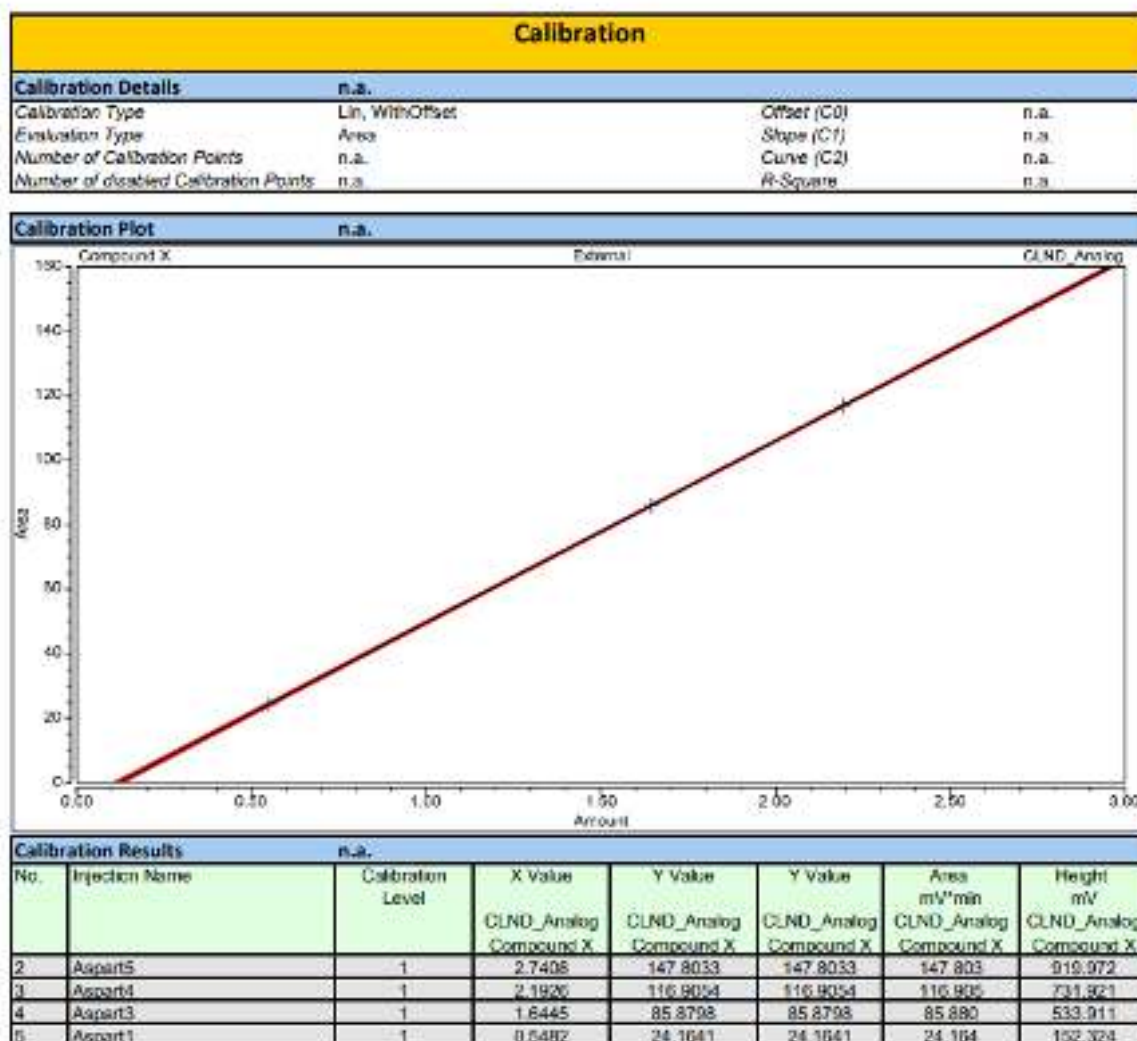
No.	Peak Name	Retention Time min	Area mV*min	Height mV	Amount ug N	Concentration mg N/ml	Evaluation
n.a.	Compound X	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
1	Compound Y	7.228	56.074	330.031	1.1145	0.2229	valid
Total:			56.074	330.031	1.11	0.22	

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Instrument: CLND-2 Sequence: 200807

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1.4 Results:

NNC: CJC-1295 +DAC (PO-202		Salt:	0
MW (calculated) g/mol	N content (calculated) %	N conc. (measured) mg × N/ml	
3647,25	18,05	0,2275	
Theoretical Volume ml		Lyophilizate amount mg	
1,00		2,00	
Peptide concentration mg/ml		Quantified amount mg	
1,26	345	1,3	345
Peptide content assay %			
63,0			

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.
CJC-1295+DAC	2	--	1,26	--	63,0%

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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 16 min, according to chromatogram results
Column: Waters Acquity BEH, C-18, 1.7µm, 2.1mm x 150mm

2.3 Sample preparation:

An aliquote of CJC-1295+DAC (2 mg) was dissolved in 1 mL of DMSO.
Injection: 0.4 µL

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2.4 Chromatogram of CJC-1295+DAC (PO-2023146)

Sample information

UPLC3

Channel Description ACQUITY TUV ChA 214nm

Vial : 1-E,8 Vol. : 0.40 ul

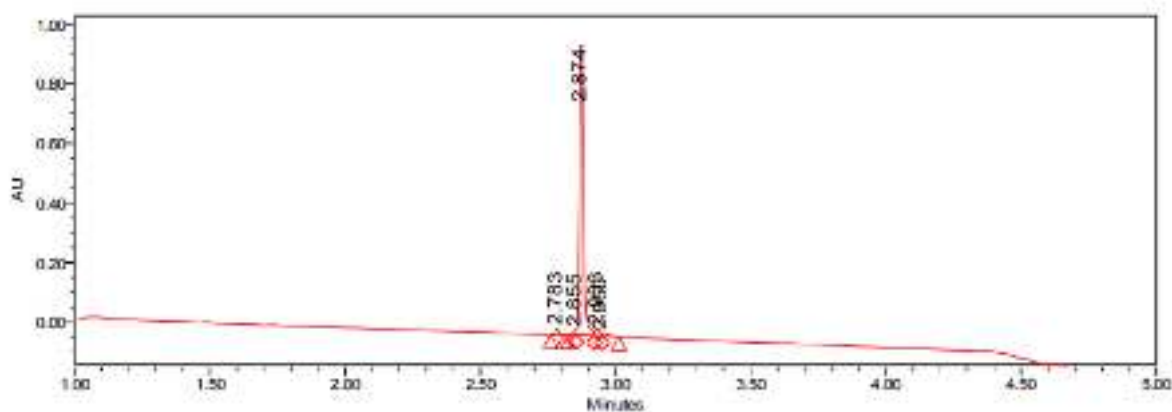
Sample: CJC1295+DAC (PO2023146)

Date Acquired 8/9/2023 10:08:15 AM CEST

Date Processed 8/9/2023 10:56:06 AM CEST

Acq Method Set :

Gr_5_60_4ml_40C_0_45_K2_met_s



	RT	Area	Height (µV)	% Area
1	2.783	17308	20395	1.72
2	2.855	11925	15994	1.19
3	2.874	834615	976113	92.93
4	2.933	30530	24764	3.04
5	2.950	11294	8732	1.12

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, 1.7µm, 2.1 x 50 mm column

column oven temp. = 40 °C

2.5 Result of purity assessment

The overall purity is 92.93 % at 214 nm.

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3. Peptide identity by UPLC/MS:

3.1 HPLC Instrument:

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

3.2 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

3.3 MS Detector:

Detector Waters (Micromass) ZQ 2000
Ionisation method: ES+
Scanning range: 200 – 2000 amu
Capillary voltage: 3.0 kV
Cone Voltage: 20 V
Scantime: 0.9 s
Interscan delay: 0.1 s
Detection method: quadrupole

3.4 Sample preparation:

An aliquote of CJC-1295+DAC (2 mg) was dissolved in 4 mL of DMSO:water (1:3).
Injection: 5.0 µL

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3.5 Mass Spectra of CJC-1295+DAC (PO-2023146)

Sample information

UPLC1 ZQ

Sample: **CJC1295+DAC (PO2023146)**

Channel Description ACQUITY TUV ChA 214nm

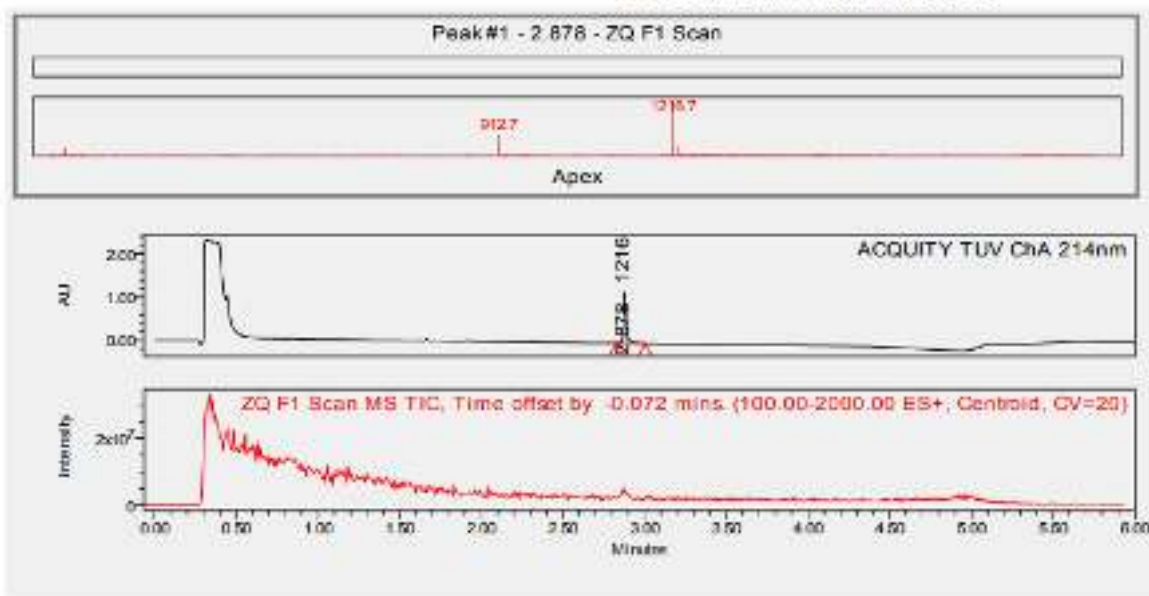
Date Acquired 8/9/2023 11:16:08 AM CEST

Vial : 1;A,8 Vol. : 5.00 ul

Date Processed 8/9/2023 2:00:22 PM CEST

Acq Method Set :

Gr5_60_MS_4min_0_45ml_K2_me_s



MS Result Table

	Name	RT	Base Peak (m/z)
1		2.878	1216.67

UPLC conditions:

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

0.45ml/min

Acquity UPLC BEHC18, 1.7µm, 2.1 x 50 mm column
column temp. = 40 °C

Theoretical values of m/z for MW 3647.3:

Peptide MW	[M+2H] ²⁺	[M+3H] ³⁺	[M+4H] ⁴⁺	[M+5H] ⁵⁺	[M+6H] ⁶⁺	[M+7H] ⁷⁺
3647.3	1824,5	1216,7	912,8	730,4	608,8	522,0
Found		1216.7	912.7			

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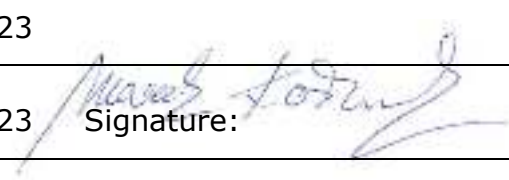
CONCLUSION:

The sample CJC-1295+DAC (Batch No. 2023146) was analyzed for peptide content, UV purity and identity by MS.

Peptide content is 63.0 % (1.26 mg in 2 mg)

Purity is 92.93 % (UPLC at 214 nm).

Identity complies with theoretical calculation of m/z values.

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

Test Certificate No.:
18060/2023

Testing laboratory

EUROFINS BELNOVAMANN s.r.o.
Kornjatická 73, 940 02 Nové Zámky
IČO: 31 329 209
Place of work:
Testing laboratory Bratislava
Kollárovo nám. 9, 811 07 Bratislava
tel.: 0911 810 533, fax: 02/52620178
CSPharmaSK@eurofins.sk, www.eurofins.sk

Customer

PARTICLE s.r.o.
Kolónada 4490/18
984 01 Lučenec

Product information No.:

18060

Sample description: endotoxin content analysis, bioburden test
Gross weight (volume): 7 ks x 2 mg
Lot/Los-Nr.: CJC-1295 + DAC

Information about Sampling:

Sampler: customer

Sample reception date: 21.07.2023 Date of Testing: 21.07.2023 - 27.07.2023 Certificate issued on: 27.07.2023

Microbiological tests

Parameter	Unit	Allowed Value	Measured Value	Uncertainty*	Testing method	E	SL	TT
Total Aerobic Microbial Count	CFU/10 mg	-	0	-	ŠPP MB.M.140.PN	-	PN	A
Total Combined Yeast/Moulds Count	CFU/10 mg	-	0	-	ŠPP MB.M.140.PN	-	PN	A
Bacterial endotoxins	U/mg	m	<0,5	-	ŠPP MB.M.140.PN	S	PN	A

Notes:

- E - evaluation
S - satisfied
NS - not satisfied
ŠPP, LS-PP, CH - Standard operation procedure
ND - not detected by given method
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 "0" at the case of 5 sample's evaluation
* - uncertainty determined by extension coefficient k=2 (with probability of 95%) does not include the uncertainty of sampling.
- uncertainty given in units of analysed parameter reflects the uncertainty to the result of measurement.
- uncertainty given in % reflects the uncertainty from the result of measurement.
SL - analysing laboratory: BA-Bratislava, PN-Piešťany
TT - type of test
(A) - accredited sampling
A - accredited test executed at the own test laboratory
N - non accredited test executed at the own test laboratory
SA - accredited test executed under the subcontract
SN - unaccredited test executed under the subcontract
TM - testing outside the laboratory at the customer

Disclaimer:

The laboratory is not responsible for the information provided by the customer, which can affect the validity of the 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 Test Certificate and marked as non-accredited test shall not be a subject of accreditation.
The result given in this Test Certificate and marked as sub-delivery is the result of a Subcontractor's gauging made under the terms and conditions of a contract concluded with him.
It's not possible reproduce or incorporate the test certificate into promotional materials without laboratory written authorization.
SNAS is a Signatory to the Multilateral Agreement VRA-ILAC.

Test results have been electronically validated by: Ing. Terézia Šolányová

Worked out by: Bc. Martin Tóth
Document No.: 8979/2023



Test Certificate approved by:
Ing. Terézia Šolányová
Specialist

Protokol o skúške č. AR-23-KT-023466-01



Názov a adresa skúšobného laboratória:

Eurofins Environment Testing Slovakia s.r.o.
 Robotnícka 820/36, 039 01 Turčianske Teplice
 IČO: 53 248 376
 Pracovisko:
Skúšobné laboratórium Turčianske Teplice
 Robotnícka 820/36, 039 01 Turčianske Teplice
 tel: 043/490 1562
 RegistrationEnviroSK@eurofins.sk, www.eurofins.sk

Názov a adresa zákazníka:

UAB Nauja oda eshop
 A. Goštauto g. 8-215
 LT-01108 Vilnius
 SLOVENSKO

Dátum prevzatia vzorky: 21.07.2023 Dátum vykonania skúšky: 21.07.2023 - 25.07.2023 Dátum vystavenia protokolu: 26.07.2023

Informácie o odbere vzorky:

Vzorku odobral: zákazník

Informácie o vzorke: 104-2023-00026596

Názov vzorky: CJC-1295 + DAC

Materiál: Peptidy

Fyzikálne a chemické skúšky

Parameter	Jednotka	Povolená hodnota	Výsledok merania	Neistota merania*	Princíp	Skúšobná metóda	H	SL	TS
Arzén (As)	mg/kg	-	<1,5	-	ICP-MS	LS-PP-CH-85	-	TR	A
Kadmium (Cd)	mg/kg	-	<0,20	-	ICP-MS	LS-PP-CH-85	-	TR	A
Nikel (Ni)	mg/kg	-	<2,0	-	ICP-MS	LS-PP-CH-85	-	TR	A
Olovo (Pb)	mg/kg	-	<0,50	-	ICP-MS	LS-PP-CH-85	-	TR	A
Ortuť (Hg)	mg/kg	-	<0,30	-	ICP-MS	LS-PP-CH-85	-	TR	A
Selén (Se)	mg/kg	-	<8,0	-	ICP-MS	LS-PP-CH-85	-	TR	A

Vysvetlivky:

H - hodnotenie
 V - vyhovuje
 NE - nevyhovuje
 (A) - akreditovaný odber
 (SA) - akreditovaný odber vykonaný subdodávateľsky
 SPP - štandardný pracovný postup
 ND - danou metódou nedetekovateľné
 LOQ, LQ – medza stanovenie metódy
 KTJ - kolóniu tvoriaca jednotka
 NM - nevyhnutné množstvo
 m - najvyššia povolená hodnota pri jednovzorkovom hodnotení
 M, c - "M" je najvyššia povolená hodnota pre počet vzoriek "c" z 5 pri päťvzorkovom hodnotení
 * - rozšírená neistota určená s koeficientom rozšírenia k=2 (s pravdepodobnosťou 95%), nezahŕňa neistotu vzorkovania.
 - rozšírená neistota uvedená v % vyjadruje neistotu z výsledku merania.
 ** - Prijateľná/ý pre spotrebiteľov a bez abnormálnych zmien
 SL - laboratórium vykonávajúce skúšku: NZ-Nové Zámky, TR-Turčianske Teplice, RK-Ružomberok, TV-Trebišov

TS - typ skúšky

A - akreditovaná skúška vykonaná vo vlastnom skúšobnom laboratóriu
 N - neakreditovaná skúška vykonaná vo vlastnom skúšobnom laboratóriu
 SA - akreditovaná skúška vykonaná subdodávateľsky
 SN - neakreditovaná skúška vykonaná subdodávateľsky
 (TM) - skúšanie mimo laboratória u zákazníka

Prehlásenie:

Laboratórium nezodpovedá za informácie dodané zákazníkom (#), ktoré môžu mať vplyv na platnosť výsledkov. Ak vzorku poskytol zákazník, výsledky sa vzťahujú ku vzorke, tak ako bola do laboratória prijatá. Meradlá a meracie zariadenia použité na skúšky boli kalibrované alebo overené v zmysle platných metrologických predpisov. Výsledky sa týkajú iba predmetu skúšok a nenahrádzajú iné dokumenty napr. správneho charakteru. Výsledok označený v tomto protokole ako neakreditovaná skúška nie je predmetom akreditácie. Výsledok označený v tomto protokole ako subdodávka je výsledkom merania subdodávateľa na základe kontraktu. Protokol môže byť reprodukován alebo včleňovaný do propagačných materiálov len s písomným súhlasom skúšobného laboratória a v rozsahu tohto súhlasu. Akékoľvek pozmeňovanie, vyhotovovanie kópií časti skúšobného protokolu je nepovolené a takýto protokol sa stáva automaticky neplatným. Overenie pravosti a úplnosti protokolu je možné na základe žiadosti vykonať na pracovisku skúšobného laboratória, ktoré je uvedené v záhlaví protokolu – „Názov a adresa skúšobného laboratória“ Laboratórium je akreditované SNAS, ktorý je signatárom EA MLA a ILAC MRA v oblasti akreditácie laboratórií.

Výsledky analýz elektronicky validoval(i):

Michaela Ruttkayová
Odborný pracovník

Vyhotovil: Andrea Podušelová

Overenie platnosti dokumentu



Protokol o skúške schválil:

Michaela Ruttkayová
Odborný pracovník

