

ANALYTICAL CERTIFICATE

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Sample name	CJC-1295 DAC
Batch No.	2024195
Sample No.	01
Sequence	Tyr-D-Ala-Asp-Ala-Ile-Phe-Thr-Gln-Ser-Tyr-Arg- Lys-Val-Leu-Ala-Gln-Leu-Ser-Ala-Arg-Lys-Leu-Leu-Gln-Asp-Ile-Leu-Ser-Arg-Lys-Lys(Maleimidopropionyl)-NH ₂
Manufacturing date	NA
Submitter of analytical request	Particle s.r.o., Slovakia

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 (5 mg) was dissolved in 1 mL of DMSO.
Injection: 3.0 μ L

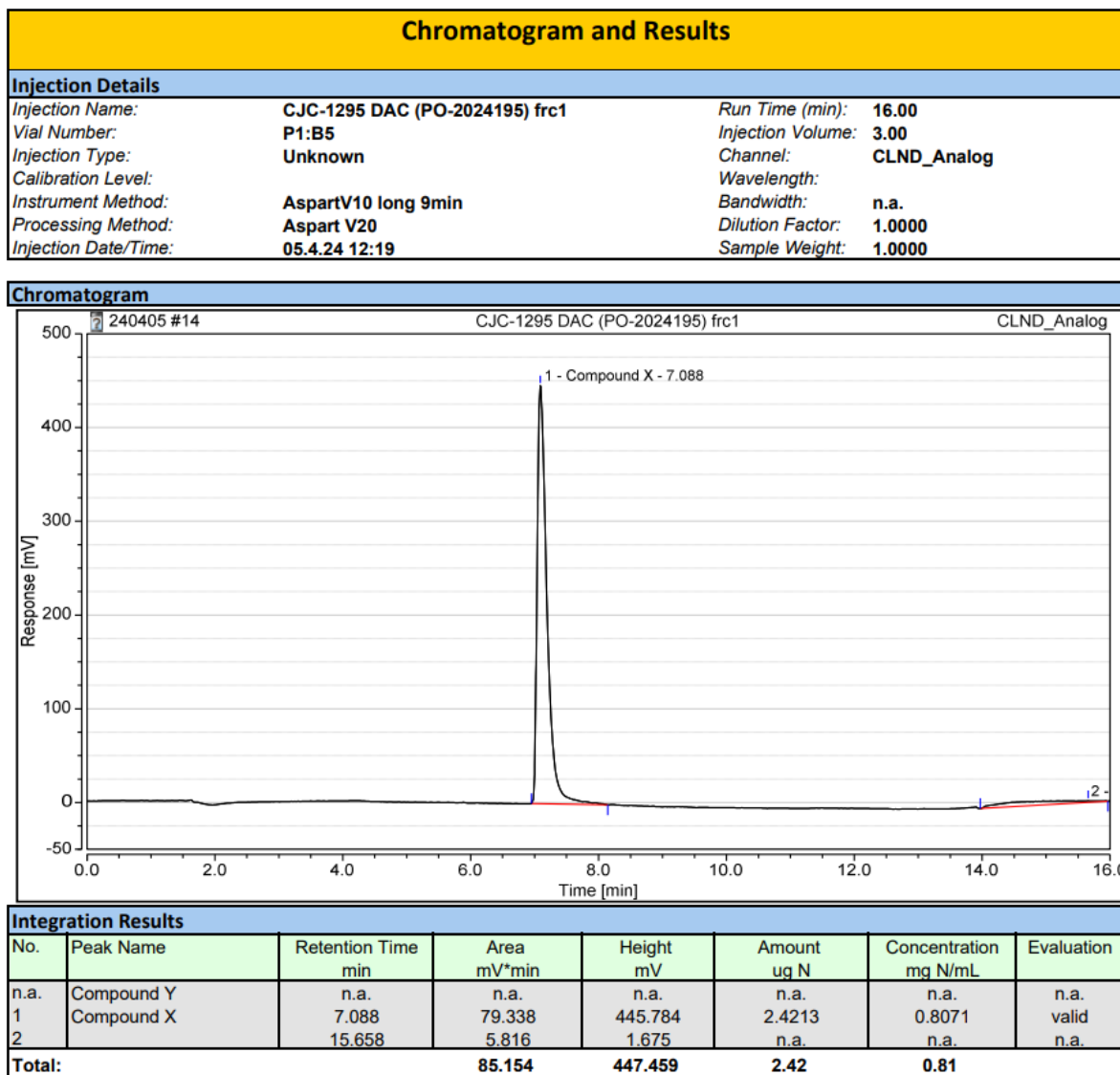
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1.4 Chromatograms and calibration curve:

Instrument:CLND-2 Sequence:240405

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Instrument:CLND-2 Sequence:240405

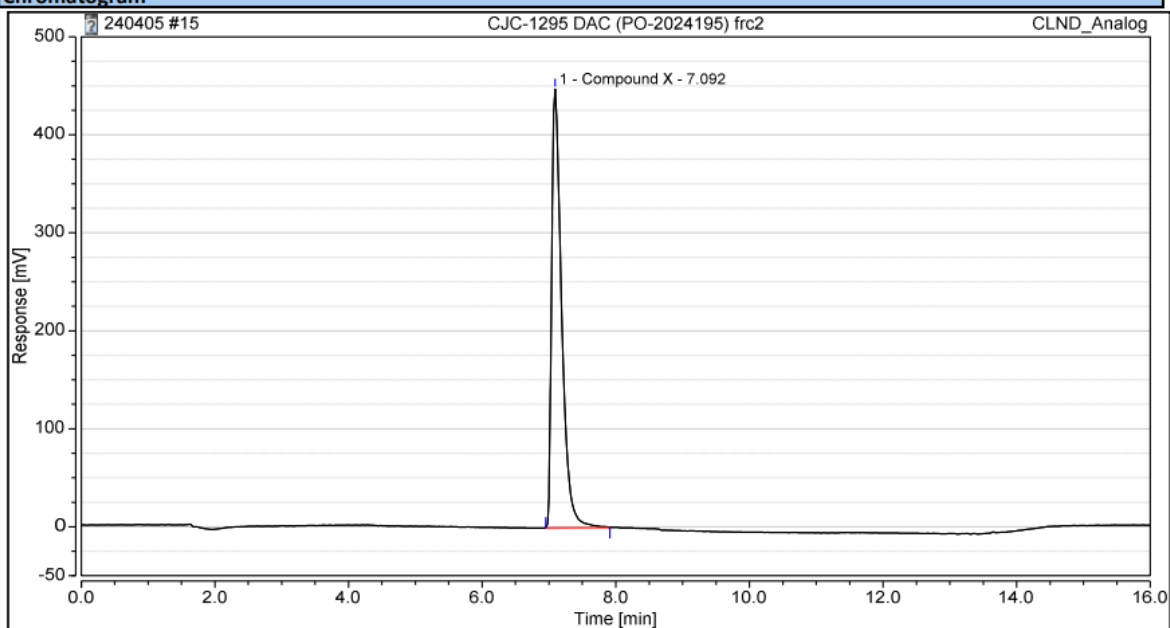
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Chromatogram and Results

Injection Details

Injection Name:	CJC-1295 DAC (PO-2024195) frc2	Run Time (min):	16.00
Vial Number:	P1:B5	Injection Volume:	3.00
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:	05.4.24 12:36	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 Y	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
1	Compound X	7.092	77.749	447.413	2.3758	0.7919	valid
Total:			77.749	447.413	2.38	0.79	

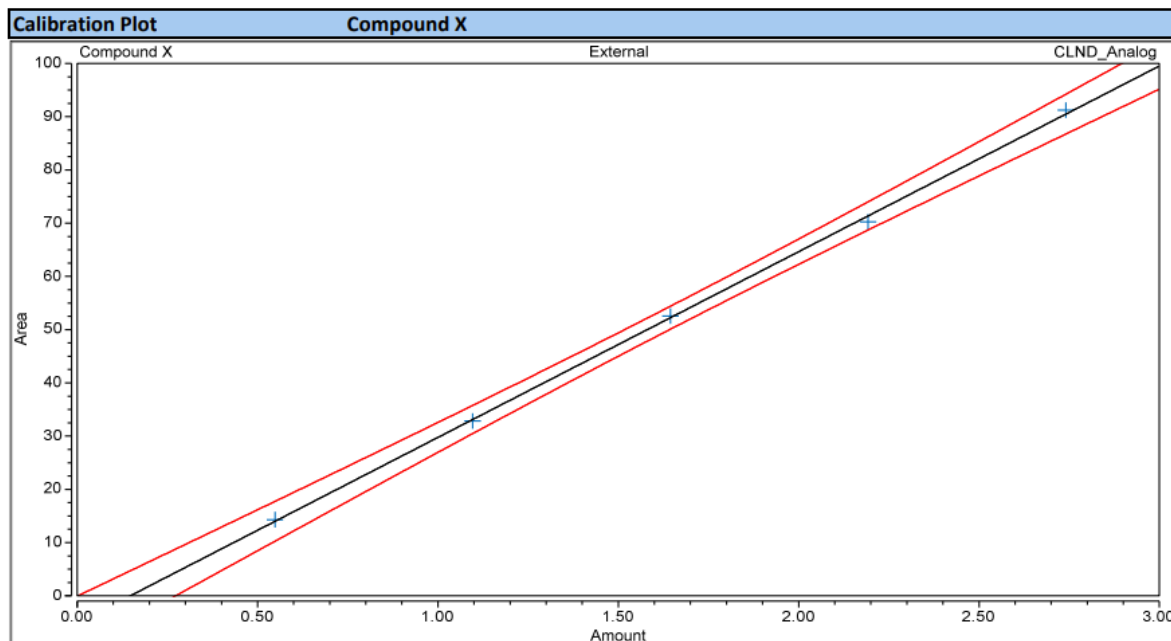
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Instrument:CLND-2 Sequence:240405

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Calibration			
Calibration Details		Compound X	
Calibration Type	Lin, WithOffset	Offset (C0)	-5.1320
Evaluation Type	Area	Slope (C1)	34.8862
Number of Calibration Points	5	Curve (C2)	0.0000
Number of disabled Calibration Points	0	R-Square	0.9994



Calibration Results		Compound X					
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	91.2238	91.2238	91.224	532.856
3	Aspart4	1	2.1926	70.2476	70.2476	70.248	415.230
4	Aspart3	1	1.6445	52.5511	52.5511	52.551	310.070
5	Aspart2	1	1.0963	32.8563	32.8563	32.856	190.430
6	Aspart1	1	0.5482	14.3049	14.3049	14.305	84.132

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1.4 Results:

NNC: CJC-1295 DAC (PO-2024		Salt:	0
MW (calculated) g/mol	N content (calculated) %	N conc. (measured) mg × N/ml	
3775,43	18,18	0,7995	
Theoretical Volume ml		Lyophilizate amount mg	
1,00		5,00	
Peptide concentration mg/ml nmol/ml		Quantified amount mg nmol	
4,40	1165	4,4	1 165
Peptide content assay %			
88,0			

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	5	NA	4,4	NA	88,0%

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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 (5 mg) was dissolved in 1 mL of DMSO.
Injection: 0.2 µL

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2.4 Chromatogram of CJC-1295 DAC (PO-2024195)

Sample information

UPLC5

Channel Description PDA Ch1 214nm@4.8nm

Vial : 1:A,8 Vol. : 0.20 ul

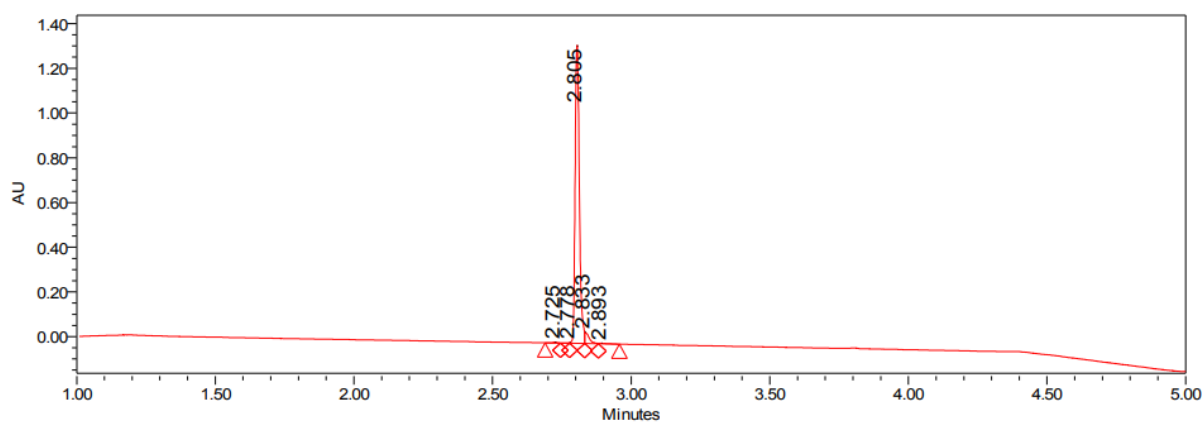
Sample: CJC-1295 DAC (PO-2024195)

Date Acquired 4/5/2024 3:07:08 PM CEST

Date Processed 4/9/2024 3:39:31 PM CEST

Acq Method Set :

Gr5_60_4mi_40C_0_45ml_K2_met_s



	RT	Area	Height (μV)	% Area
1	2.725	4985	3663	0.34
2	2.778	2470	2330	0.17
3	2.805	1404609	1335851	95.43
4	2.833	54853	52233	3.73
5	2.893	4970	2599	0.34

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 own temp. = 40 °C

2.5 Result of purity assessment

The overall purity is 95.43 % at 214 nm.

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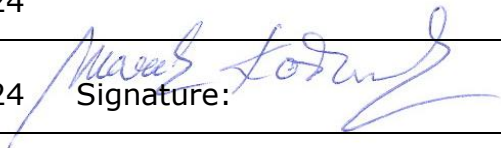
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CONCLUSION:

The sample CJC-1295 DAC (Batch No. 2024195) was analyzed for peptide content and UV purity.

Peptide content is 88.0 % (4.4 mg in 5 mg)

Purity is 95.43 % (UPLC at 214 nm).

ANALYSIS COMPLETED:	Date: 05.04.2024
Issued by QC:	Date: 10.04.2024 Signature: 

Test Certificate No.: 3304/2024
Replaces Test Certificate 3304/2024

Testing laboratory Eurofins BioPharma Product Testing Slovakia s.r.o. Radlinského 9, 811 07 Bratislava IČO: 31 329 209 Place of work: Testing laboratory Bratislava Kollárovo nám. 9, 811 07 Bratislava Tel.: 0911 810 533 cspharmask@bpt.eurofinseu.com, www.eurofins.sk	Customer PARTICLE s.r.o. Kolonada 4490/18 984 01 Lučenec
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Product information No.: 3304
Sample description: CJC-1295 DAC (PO-2024195)
Gross weight (volume): 5 mg glass vials

Information about Sampling:
Sampler: customer

Sample reception date: 25.03.2024 **Date of Testing:** 25.03.2024 - 04.04.2024 **Certificate issued on:** 05.04.2024

Microbiological tests

Parameter	Unit	Allowed Value	Measured Value	Uncertainty*	Testing method	E	SL	TT
Total Aerobic Microbial Count	CFU /5mg	-	0	-	ŠPP MB.M.140.PN	-	PN	A
Total Combined Yeasts/Moulds Count	CFU /5mg	-	0	-	ŠPP MB.M.140.PN	-	PN	A
Bacterial endotoxins	IU / mg	-	<0,5	-	ŠPP MB.M.146.PN	-	PN	A

Notes:

E - evaluation	TT - type of test
S - satisfied	(A) - accredited sampling
NS - not satisfied	A - accredited test executed at the own test laboratory
ŠPP, LS-PP-CH - Standard operation procedure	N - non accredited test executed at the own test laboratory
ND - not detected by given method	SA - accredited test executed under the subcontract
CFU - Colony forming unit	SN - unaccredited test executed under the subcontract
NM - necessary quantity	TM - testing outside the laboratory at the customer
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	
* - 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	

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!

Test results have been electronically validated by: Ing. Zuzana Šperková, PhD.

Worked out by: Ing. Zuzana Šperková, PhD.
Document No.: 2437/2024

 **BioPharma**
Product Testing
Eurofins BioPharma Product Testing Slovakia s.r.o.
Radlinského 9, 811 07 Bratislava
IČO: 31329209 DIČ: 2020297697
IČ DPH: SK2020297697

Test Certificate approved by:
Ing. Zuzana Šperková, PhD.
Deputy Head of Testing Laboratory

Analytical report AR-24-KT-043640-02



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: 104-2024-00048107

Sample description: CJC-1295 DAC (PO-2024195)

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
 TT - type of test
 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:

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