

ANALYTICAL CERTIFICATE

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Sample name	DSIP
Batch No.	2023166
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 DSIP (10 mg) was dissolved in 1 mL of DMSO.
Injection: 1.0 μ L

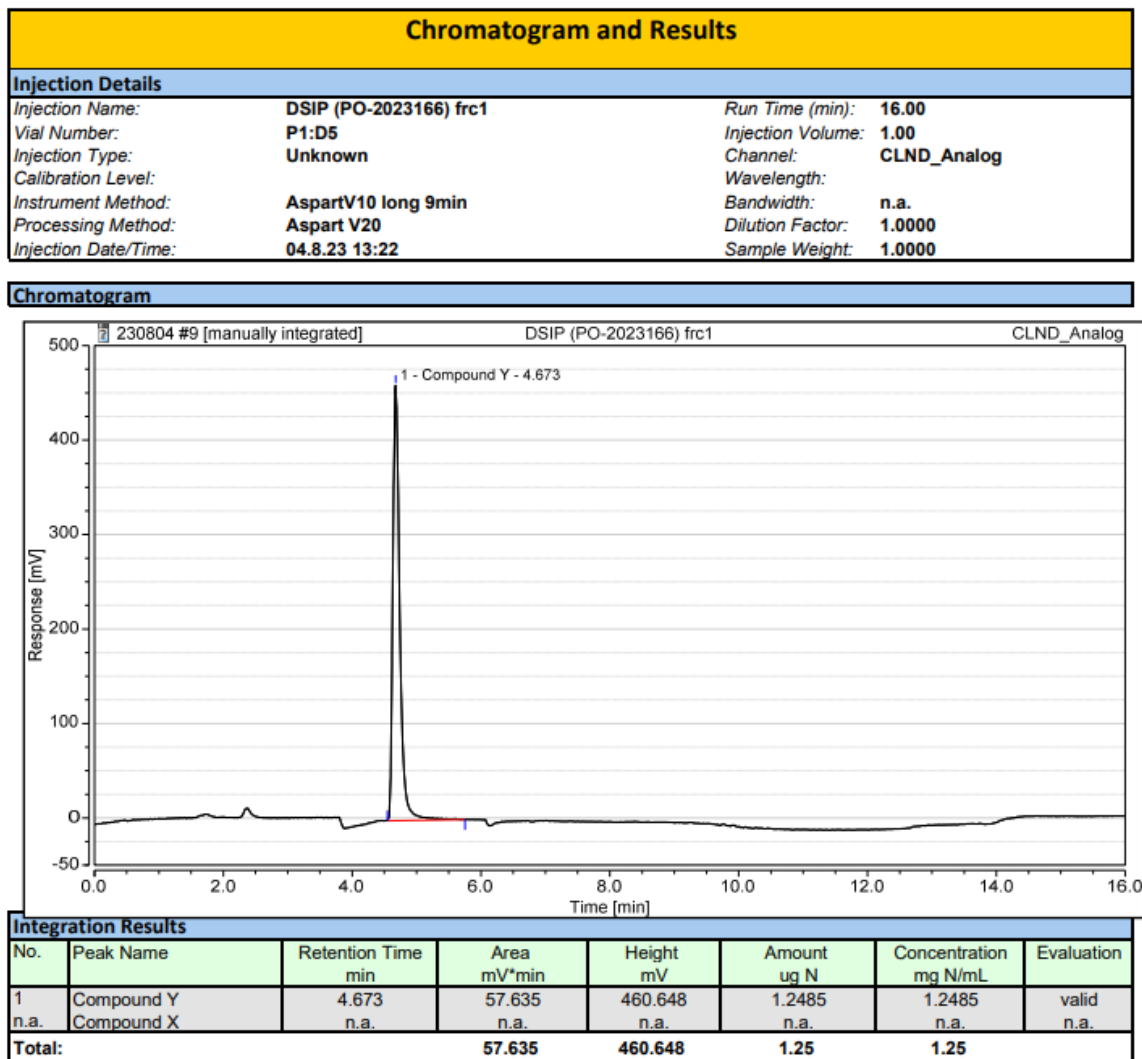
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1.4 Chromatograms and calibration curve:

Instrument: CLND-2 Sequence: 230804

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Instrument:CLND-2 Sequence:230804

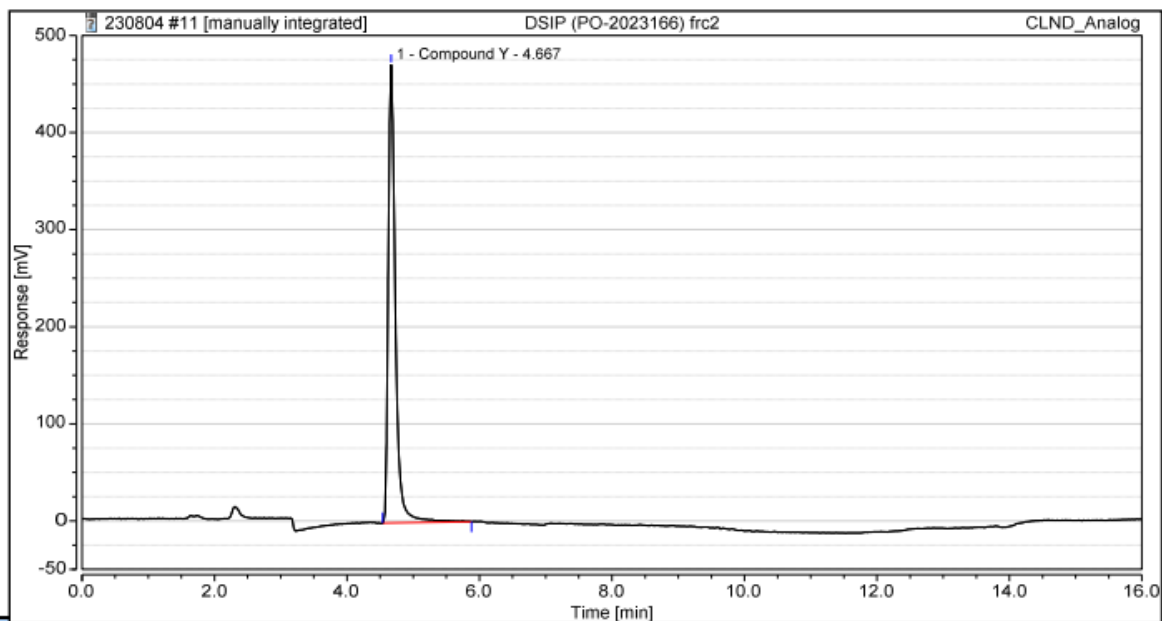
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Chromatogram and Results

Injection Details

Injection Name:	DSIP (PO-2023166) frc2	Run Time (min):	16.00
Vial Number:	P1:D5	Injection Volume:	1.00
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:	04.8.23 13:56	Sample Weight:	1.0000

Chromatogram



Integration Results

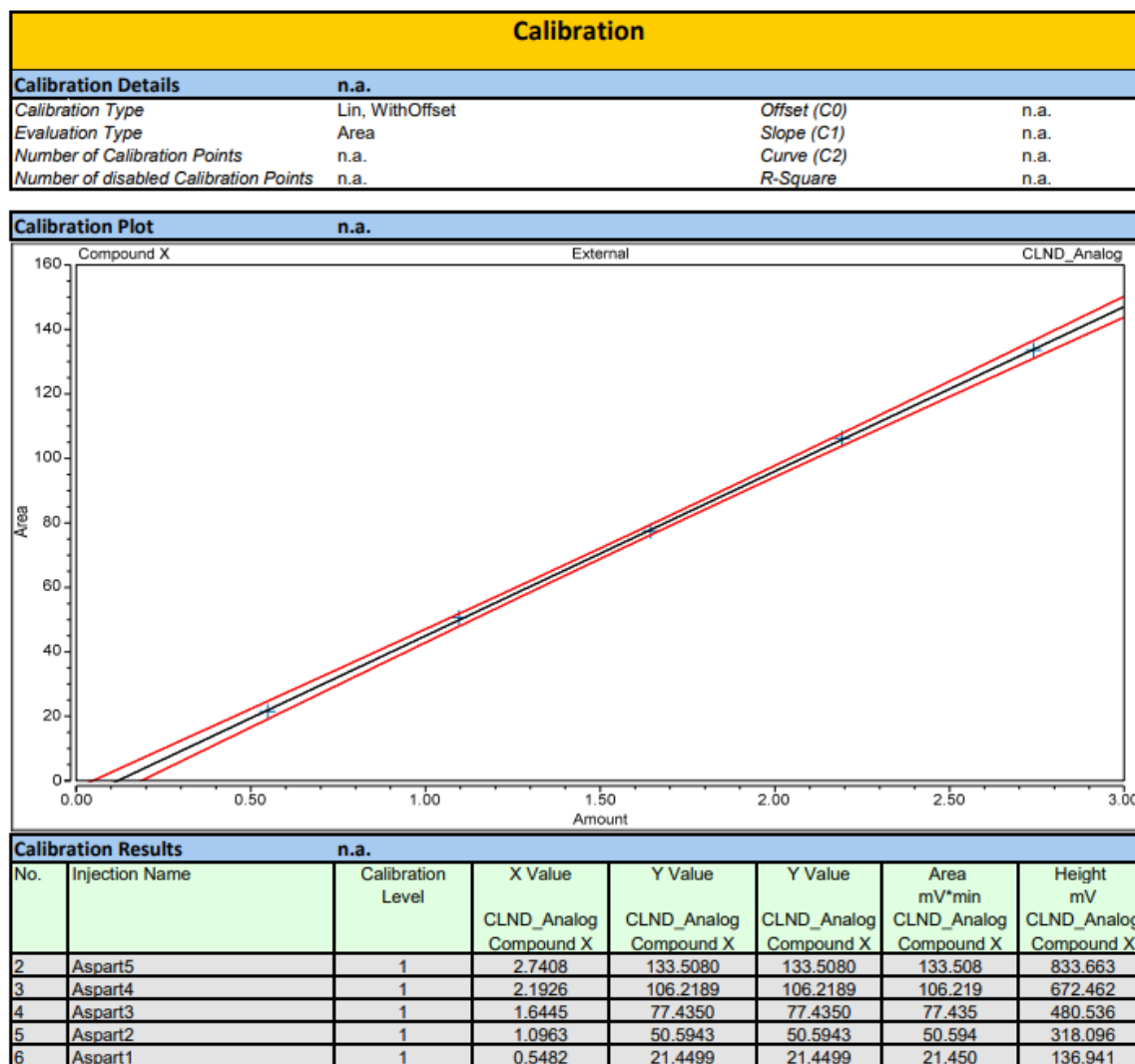
No.	Peak Name	Retention Time min	Area mV*min	Height mV	Amount ug N	Concentration mg N/mL	Evaluation
1	Compound Y	4.667	59.334	471.847	1.2818	1.2818	valid
n.a.	Compound X	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Total:			59.334	471.847	1.28	1.28	

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Instrument: CLND-2 Sequence: 230804

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1.4 Results:

NNC: DSIP (PO-2023166)		Salt:	0
MW (calculated) g/mol	N content (calculated) %	N conc. (measured) mg × N/ml	
848.82	16.5	1.2652	
Theoretical Volume ml		Lyophilizate amount mg	
1.00		10.00	
Peptide concentration mg/ml		Quantified amount mg	
	nmol/ml		nmol
7.67	9033	7.7	9,033
Peptide content assay %			
76.7			

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.
BPC-157	10	--	7,67	--	76,7 %

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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 DSIP (3 mg) was dissolved in 1 mL of water.
Injection: 0.4 µL

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2.4 Chromatogram of DSIP (PO-2023166)

Sample information

UPLC2

Channel Description ACQUITY TUV ChA 214nm

Vial : 1:B,7 Vol. : 0.40 ul

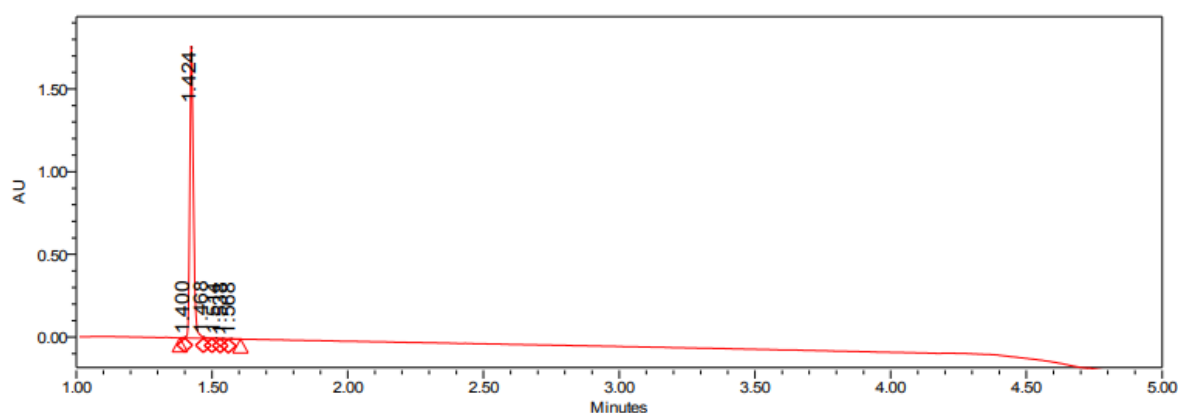
Sample: DSIP (PO-2023166)

Date Acquired 8/4/2023 2:50:51 PM CEST

Date Processed 8/4/2023 3:27:44 PM CEST

Acq Method Set :

Gr_5_60_4mi_40C_0_45_K2_met_s



	RT	Area	Height (μV)	% Area
1	1.424	1666118	1771944	98.81
2	1.468	6918	8257	0.41
3	1.514	5409	4929	0.32
4	1.538	2825	2528	0.17
5	1.568	2673	2804	0.16

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 98.81 % at 214 nm.

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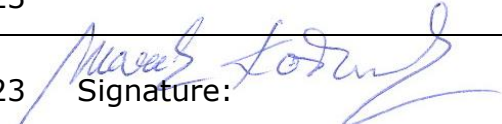
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CONCLUSION:

The sample DSIP (Batch No. 2023166) was analyzed for peptide content, acetic acid content, UV purity and identity by MS.

Peptide content is 76.7 % (7.67 mg in 10 mg)

Purity is 98.81 % (UPLC at 214 nm).

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

Analytical report AR-24-KT-043643-02



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: 104-2024-00048110

Sample description: DSIP (PO-2023166)

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