

# ANALYTICAL CERTIFICATE

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<b>Sample name</b>	<b>SS-31</b>
<b>Batch No.</b>	<b>2024252</b>
<b>Sample No.</b>	<b>01</b>
<b>Sequence</b>	DArg-Dmt-Lys-Phe-NH <sub>2</sub>
<b>Manufacturing date</b>	<b>NA</b>
<b>Submitter of analytical request</b>	<b>Particle s.r.o., Slovakia</b>

## 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 $\mu$  C4-BIO 300 A, 4.6 x 100 mm  
Serial No 221258

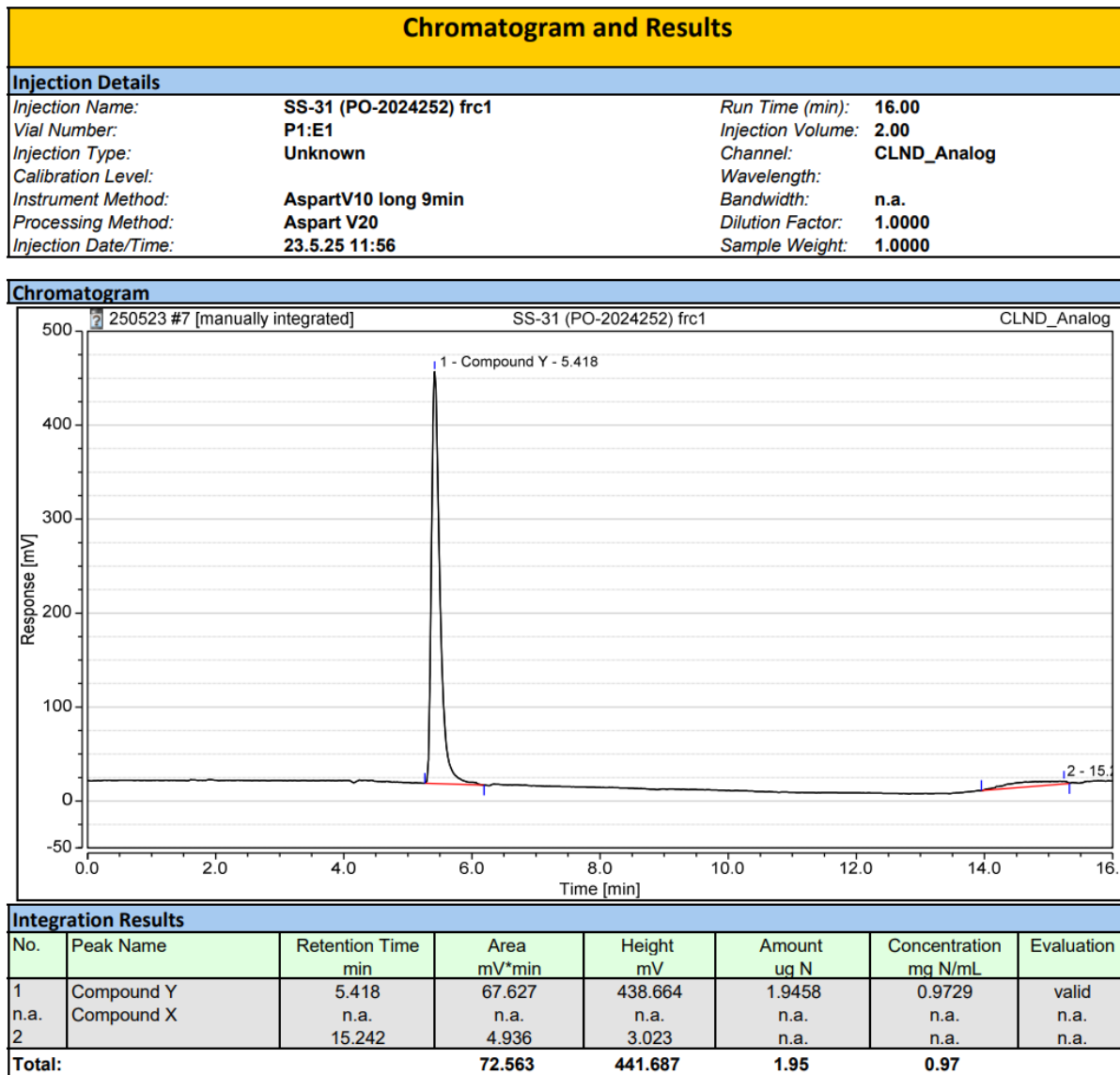
### 1.3 Sample preparation:

The whole amount of SS-31 (50 mg) was dissolved in 10 mL of MilliQ water.  
Injection: 2.0  $\mu$ L

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## 1.4 Chromatograms and calibration curve:



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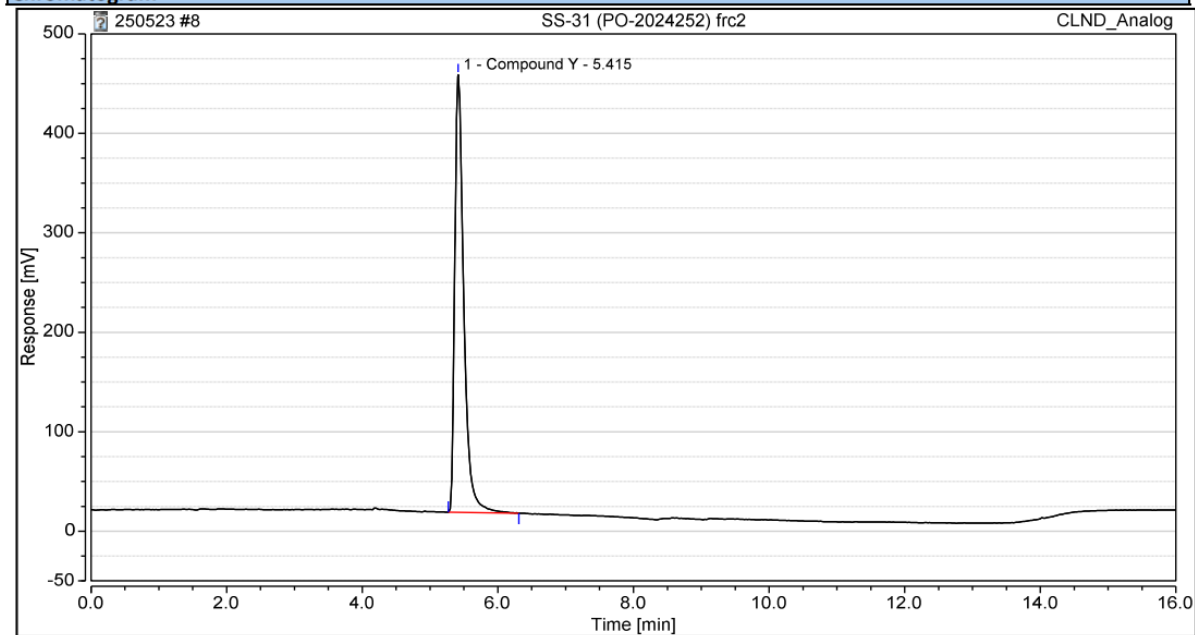
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## Chromatogram and Results

### Injection Details

Injection Name:	SS-31 (PO-2024252) frc2	Run Time (min):	16.00
Vial Number:	P1:E1	Injection Volume:	2.00
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:	23.5.25 12:13	Sample Weight:	1.0000

### Chromatogram

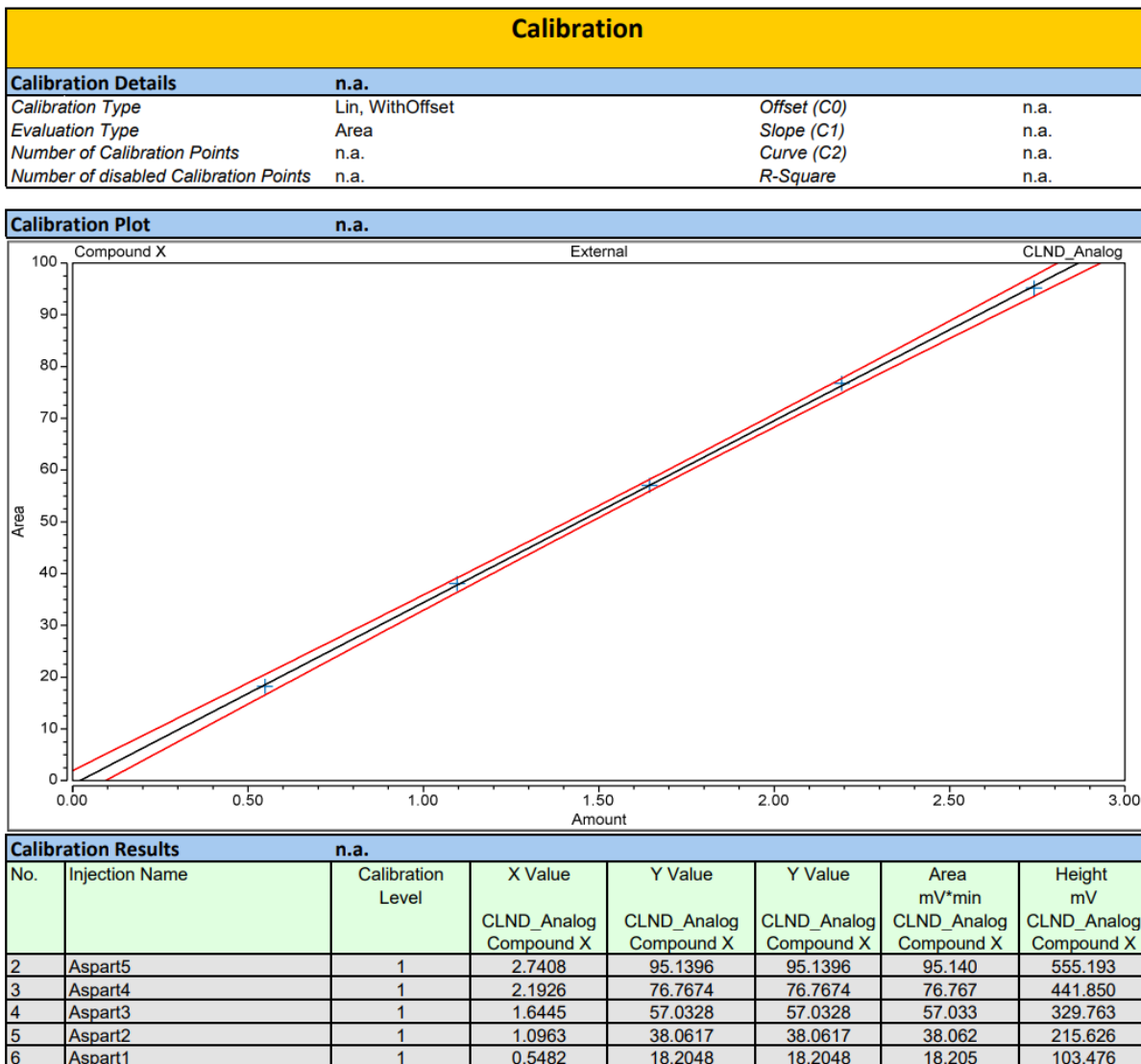


### Integration Results

No.	Peak Name	Retention Time min	Area mV*min	Height mV	Amount ug N	Concentration mg N/mL	Evaluation
1	Compound Y	5.415	68.040	439.948	1.9575	0.9788	valid
n.a.	Compound X	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
<b>Total:</b>			<b>68.040</b>	<b>439.948</b>	<b>1.96</b>	<b>0.98</b>	

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## 1.4 Results:

NNC: SS-31 (PO-2024252)		Salt:	0
MW <i>(calculated)</i> g/mol	N content <i>(calculated)</i> %	N conc. <i>(measured)</i> mg × N/ml	
639,8	19,7	0,9759	
Theoretical Volume ml		Lyophilizate amount mg	
10,00		50,00	
Peptide concentration mg/ml		Quantified amount mg	
4,95	7742	49,5	77 423
Peptide content assay %			
99,1			

## 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.
SS-31	50	--	<b>49,54</b>	--	99,1 %

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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 SS-31 (1 mg) was dissolved in 1 mL of water.  
Injection:                1.0 µL

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## 2.4 Chromatogram of SS-31 (PO-2024252)

### Sample information

#### UPLC5

Channel Description PDA Ch1 214nm@4.8nm

Vial : 1:A,3 Vol. : 1.00 ul

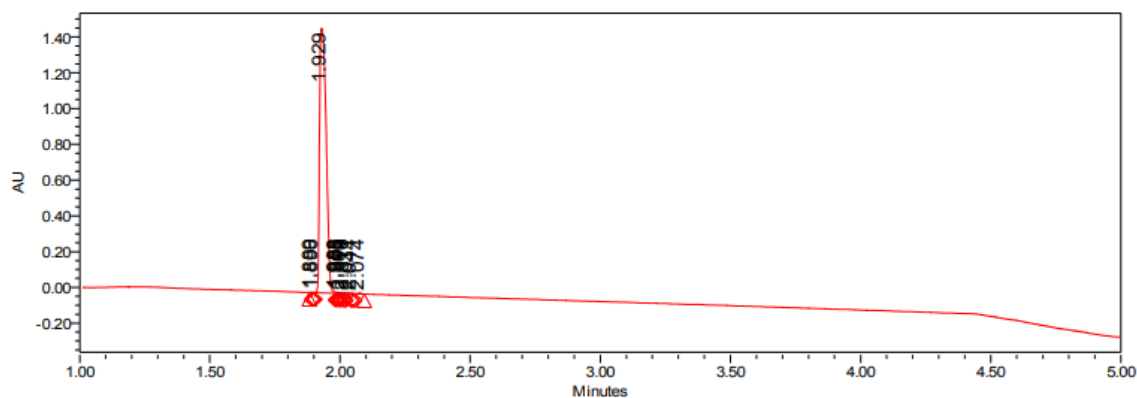
**Sample: SS-31 (PO-2024252)**

Date Acquired 5/26/2025 1:04:03 PM CEST

Date Processed 5/26/2025 2:53:36 PM CEST

Acq Method Set :

Gr5\_60\_4mi\_40C\_0\_45ml\_K2\_met\_s



	RT	Area	Height (μV)	% Area
1	1.929	2599351	1477324	99.51

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 99.51 % 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 SS-31 (1 mg) was dissolved in 1 mL of water.  
Injection:                      0.8 µL

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## 3.5 Mass Spectra of SS-31 (PO-2024252)

### Sample information

#### UPLC1 ZQ

Sample: **SS-31 (PO-2024252)**

Channel Description ACQUITY TUV ChA 214nm

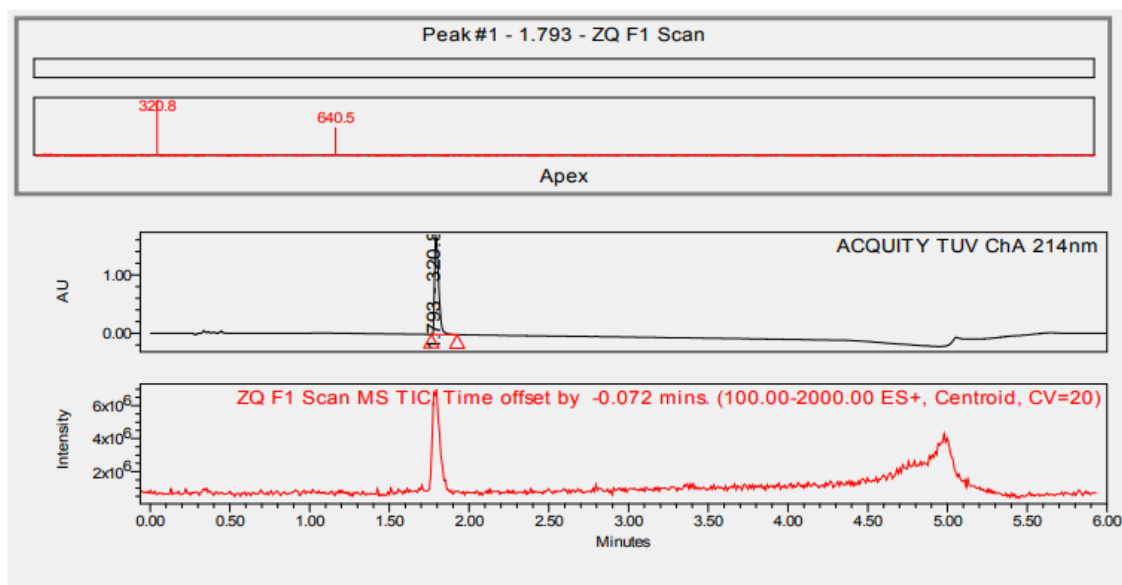
Date Acquired 5/26/2025 1:10:13 PM CEST

Vial : 1:A,2 Vol. : 0.80 ul

Date Processed 5/26/2025 2:55:10 PM CEST

Acq Method Set :

Gr5\_60\_MS\_4min\_0\_45ml\_K2\_me\_s



**MS Result Table**

	Name	RT	Base Peak (m/z)
1		1.793	320.82

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, 1.7um, 2.1 x 50 mm column

column temp. = 40 °C

Theoretical values of m/z:

Peptide MW	[M+1H] <sup>2+</sup>	[M+2H] <sup>3+</sup>	[M+3H] <sup>4+</sup>	[M+4H] <sup>5+</sup>	[M+5H] <sup>6+</sup>	[M+6H] <sup>7+</sup>
639,8	640,8	320,9				
Found	640,5	320,8				

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### 4. Endotoxin test:

#### 4.1 Description:

Test tubes: Gel Clot Lyophilized Amebocyte Lysate Single Test in Vial  
Manufacturer: Xiamen Bioendo Technology Co., Ltd.  
Lot: 24061152  
Content: 0.2 ml endotoxin-specific Amebocyte Lysate which includes beta-glucan inhibitor in the formulation  
Sensitivity of test: 0.5 EU/mL  
Sample sensitivity level: 5 EU/mg

#### 4.2 Sample preparation and test:

A sample peptide is dissolved in endotoxin-free water to form a concentration of 0.5 mg/mL. 200  $\mu$ L of this solution is then transferred to the Amebocyte Lysate Single Test tube and incubated at 37 °C for 60 min. Immediately after incubation the test tube is slowly turned upside down.

A solid gel clot which doesn't come down immediately indicates **positive** result (meaning that endotoxins are above the current sensitivity level).

An absence of solid gel clot so the solution freely flows down from the bottom of test tube indicates **negative** result (meaning that endotoxin are below the current sensitivity level).

#### 4.3 Result:

NEGATIVE (-)

#### CONCLUSION:

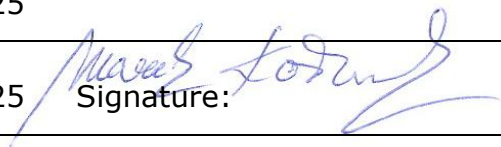
**The sample SS-31 (Batch No. 2024252) was analyzed for peptide content, acetic acid content, UV purity, identity by MS and endotoxins.**

**Peptide content is 99.08 % (49.54 mg in 50 mg)**

**Purity is 99.51 % (UPLC at 214 nm).**

**MS identity complies with theoretical calculation of m/z values.**

**Endotoxin test (sensitivity level 5 EU/mg) - NEGATIVE.**

<b>ANALYSIS COMPLETED:</b>	Date: 26.05.2025
<b>Issued by QC:</b>	Date: 27.05.2025 Signature: 

# Certificate Of Analysis



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**Client:****Particle Peptides**

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**Laboratory:****Liquilabs s.r.o.**

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14000 Michle  
Czechia  
[www.liquilabs.cz](http://www.liquilabs.cz)

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## Sample Identification

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<b>Sample Name</b>	SS-31 50 mg	<b>Batch Number</b>	2025252	<b>Date Published</b>	2025-07-29 12:36
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## Results for Lyo-0065

Bioburden	Result	Unit	Uncertainty	Reporting Limit	
Total Aerobic Microbial Count USP <61> Plate Count Method	Not detected	CFU/g		>= 1000	△
Total Yeast and Mold Count USP <61> Plate Count Method	Not detected	CFU/g		>= 100	△

# Attachments for Lyo-0065

	<b>Method Specification</b>	
<b>Determination of bioburden of lyophilized samples</b>		
<i>Document number</i> <b>MIC_001_2025</b>	<i>Superseded document</i> -	<i>Number of pages</i> 2

## 1. Instrumentation and chemicals

### 1.1. Instruments used

- Sterile Syringe 2mL Luer
- Sterile needles
- Ready made PCA Plate ROTI Aquatest
- Ready made Sab4 Plate ROTI Aquatest

### 1.2. Chemicals

Sterile physiological solution (0.9% NaCl)

## 2. Sample preparation and inoculation

### 2.1 Sample preparation

1. Fresh sterile needle and syringe was used for measuring exactly 2 mL of sterile physiological solution.
2. Needle was changed and by new needle rubber top of peptide container was penetrated and 2 mL of sterile physiological solution was dispensed.
3. Content of container was completely dissolved and left for 5 minutes to settle potentially created bubbles.
4. This procedure is repeated for two vials.

### 2.2 Total Aerobic microbial count inoculation and cultivation

1. By sterile needle 1 mL of solution was filled into the sterile syringe.
2. Needle was placed above the flame for few seconds to sterilize.
3. Consequently 1 mL of solution was poured into the ready to use sterile petri dish filled with PCA agar and petri dish was closed.
4. Proces was repeated for two petri dishes.
5. With sterile needle, 1 mL of sterile physiological solution was filled into the sterile needle and was inoculated onto one sterile petri dish filled with PCA agar as negative control sample.
6. Samples and negative control sample were placed in incubator at temperature 37°C for 120h.

1

Attachment for Lyo-0065  
Filename: Bioburden-images-0.jpg

### 2.3 Total Yeast and Mold count inoculation and cultivation

1. By sterile needle 1 mL of solution was filled into the sterile syringe.
2. Needle was placed above the flame for few seconds to sterilize.
3. Consequently 1 mL of solution was poured into the ready to use sterile petri dish filled with Sab4 agar and petri dish was closed.
4. Proces was repeated for two petri dishes.
5. With sterile needle, 1 mL of sterile physiological solution was filled into the sterile needle and was inoculated onto one sterile petri dish filled with Sab4 agar as negative control sample.
6. Samples and negative control sample were placed in incubator at temperature 25°C for 72h.

## 3. Evaluation of results

After incubation time, colonies are counted as cfu (colonies forming units) and result per 1g of sample is determined as:

$$CFU_{avg} = \frac{\sum CFU_n}{n}$$

$CFU_{avg}$  = average CFU counted form  $n$  inoculations

$CFU_n$  = CFU counted per inoculation

$n$  = number of inoculations

$$CFU \text{ per gram} = \frac{CFU_{avg}}{m_s} * DF$$

$CFU_{avg}$  = Average CFU counted from  $n$  inoculations

$m_s$  = mass of sample (mg)

$DF$  = Dilution factor

If negative control sample is evaluated as positive, process have to be repeated due to possible contamination in the process of inoculation or incubation.

2

Attachment for Lyo-0065  
Filename: Bioburden-images-1.jpg

## Responsibles



**Mr. Ján Galbavý**  
Founder/Manager

Analysis results relate only to the samples tested.

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## Analytical report AR-25-KT-018095-02



### 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  
 Registration EnviroSK@etcee.eurofins.com, www.eurofins.sk

### Customer:

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

Date of Sample Receipt: 20.05.2025 Date of Testing: 20.05.2025 - 22.05.2025

Issue date: 22.05.2025

### Information about Sampling:

Sampler: customer  
 Sample information: **104-2025-00019379**  
 # Sample description: SS-31 (PO-2024252)  
 Material: Peptidy

### Physical and chemical tests

Parameter	Unit	Allowed Value	Measured Value	Uncertainty of Method measurement*	Method	Testing method	E	SL	TT
Arsenic (As)	mg/kg	max, 1,5	0,039	25%	ICP-MS	LS-PP-CH-85	S	TR	A
Cadmium (Cd)	mg/kg	max, 0,2	<0,10	-	ICP-MS	LS-PP-CH-85	S	TR	A
Lead (Pb)	mg/kg	max, 0,5	<0,30	-	ICP-MS	LS-PP-CH-85	S	TR	A
Mercury (Hg)	mg/kg	max, 0,3	0,018	25%	ICP-MS	LS-PP-CH-85	S	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

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

\* - 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: Zuzana Kubisová

Validity check of document



**Test Certificate approved by**

Michaela Ruttkayová  
Specialist worker

