

ANALYTICAL CERTIFICATE

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Sample name	PINEALON
Batch No.	2025266
Sample No.	01
Sequence	Glu-Asp-Arg
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

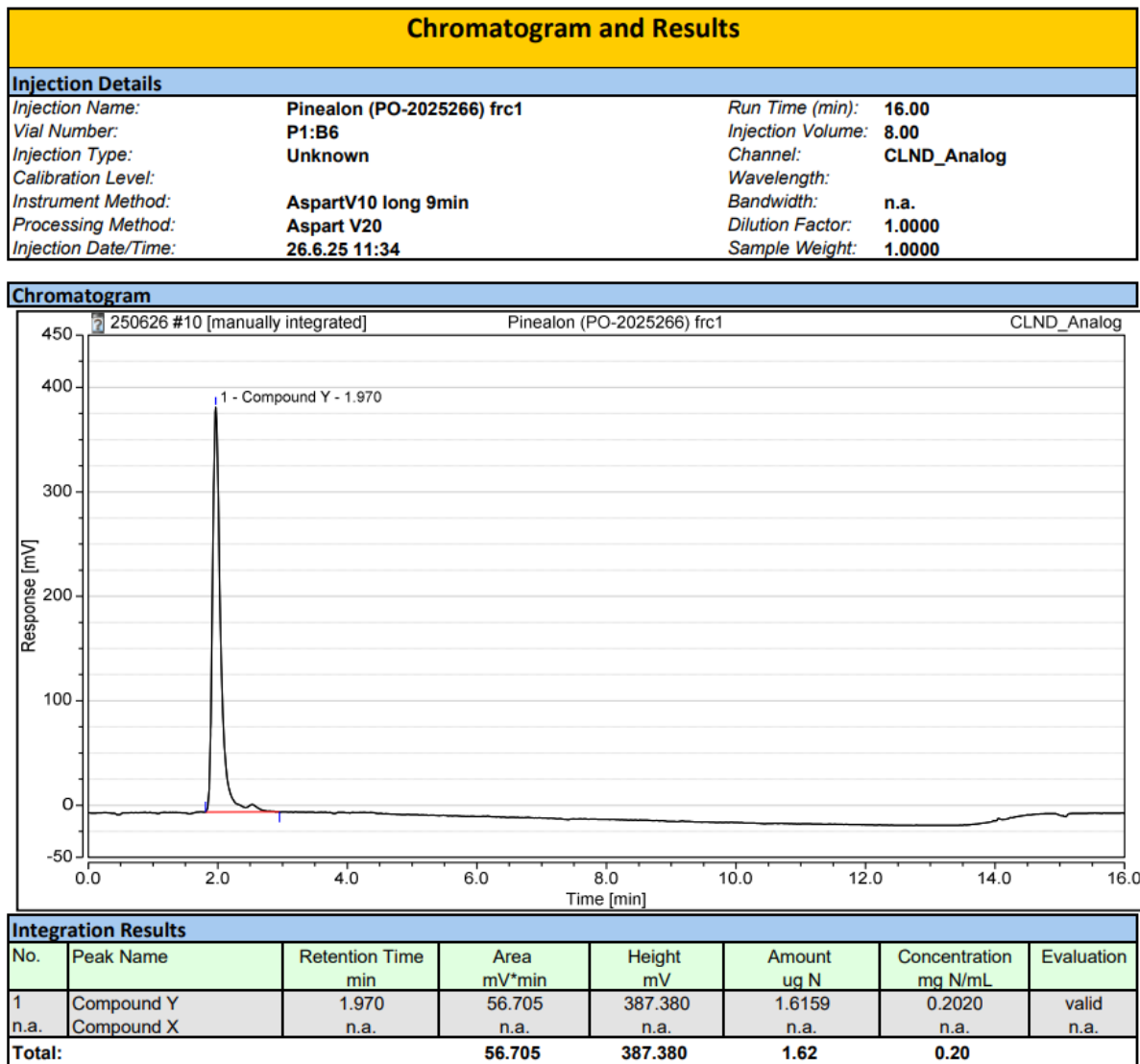
1.3 Sample preparation:

The whole amount of PINEALON (10 mg) was dissolved in 10 mL of MiliQ water.
Injection: 8.0 μ L

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1.4 Chromatograms and calibration curve:



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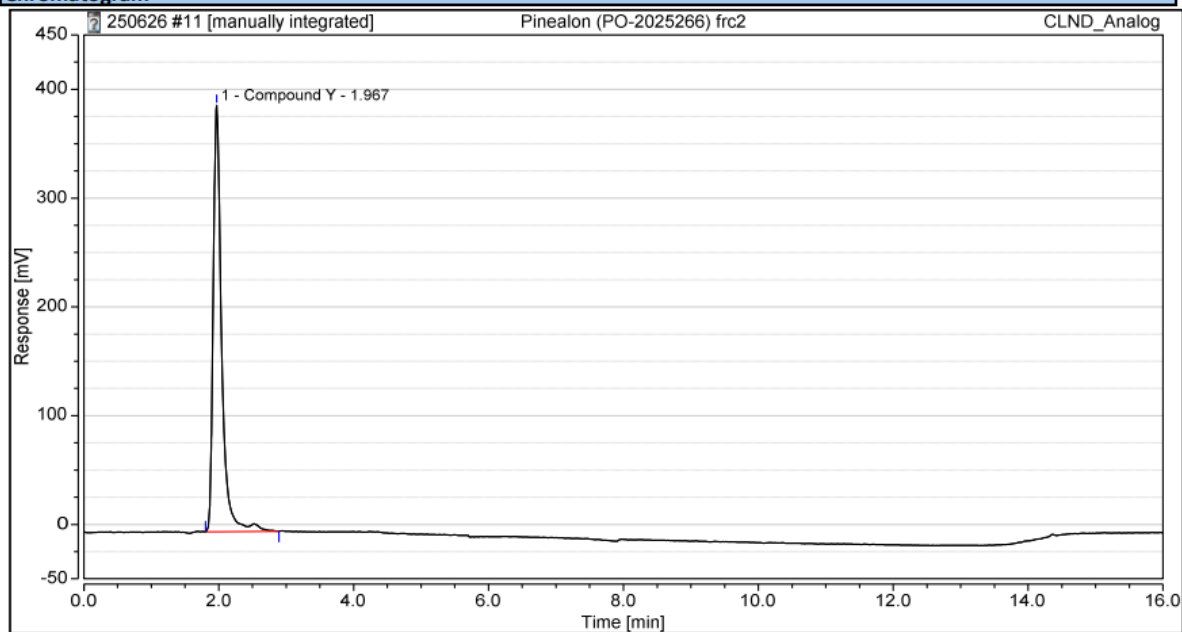
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Chromatogram and Results

Injection Details

Injection Name:	Pinealon (PO-2025266) frc2	Run Time (min):	16.00
Vial Number:	P1:B6	Injection Volume:	8.00
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:	26.6.25 11:50	Sample Weight:	1.0000

Chromatogram

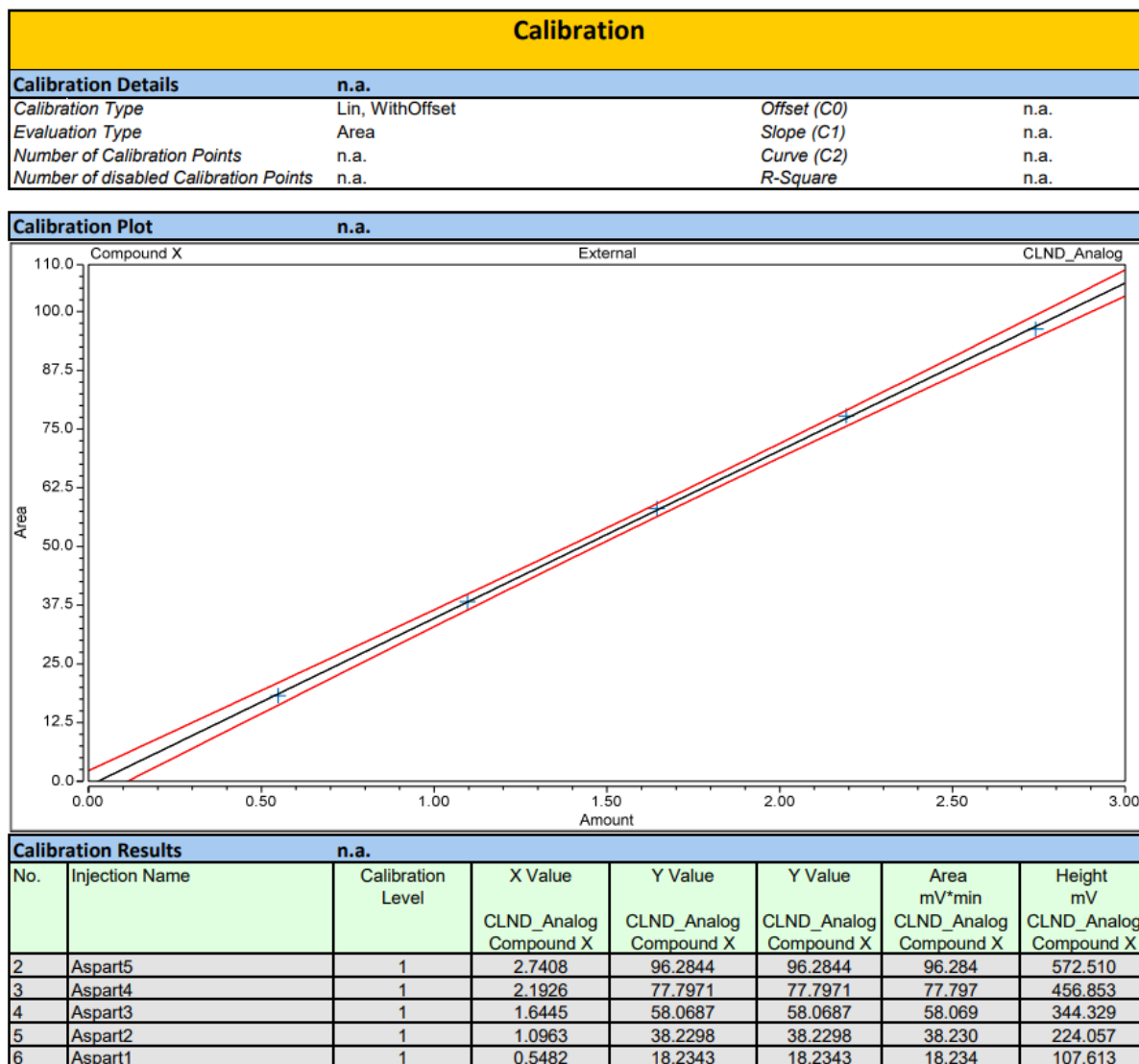


Integration Results

No.	Peak Name	Retention Time min	Area mV*min	Height mV	Amount ug N	Concentration mg N/mL	Evaluation
1	Compound Y	1.967	56.864	392.065	1.6204	0.2026	valid
n.a.	Compound X	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Total:			56.864	392.065	1.62	0.20	

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1.4 Results:

NNC: Pinealon (PO-2025266)		Salt:	0
MW <i>(calculated)</i> g/mol	N content <i>(calculated)</i> %	N conc. <i>(measured)</i> mg × N/ml	
418,41	20,09	0,2023	
Theoretical Volume ml		Lyophilizate amount mg	
10,00		10,00	
Peptide concentration mg/ml		Quantified amount mg	
1,01	2407	10,1	24 067
Peptide content assay %			
100,7			

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.
Pinealon	10	--	10,07	--	100,7 %

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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 PINEALON (1 mg) was dissolved in 1 mL of MilliQ water.
Injection: 6.0 µL

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2.4 Chromatogram of PINEALON (PO-2025266)

Sample information

UPLC1 ZQ

Channel Description ACQUITY TUV ChA 214nm

Vial : 1:A,3 Vol. : 6.00 ul

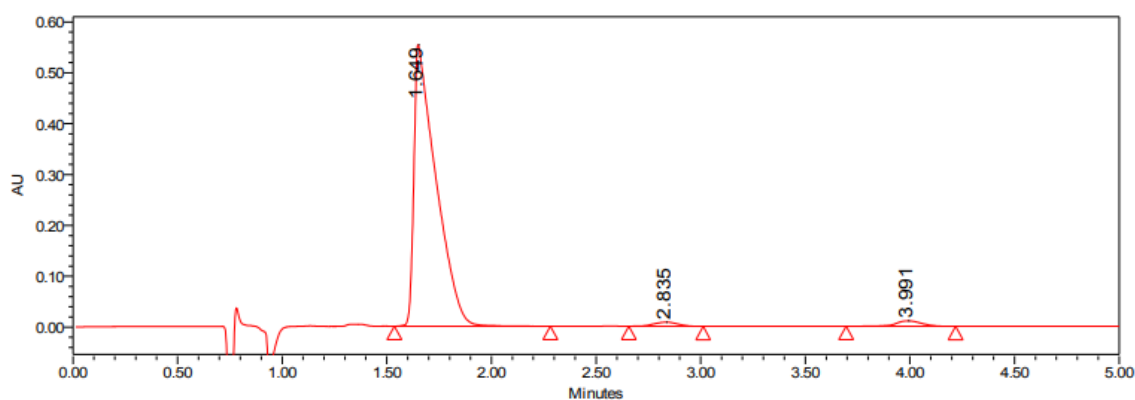
Sample: Pinealon (PO-2025266)

Date Acquired 6/27/2025 9:09:33 AM CEST

Date Processed 6/27/2025 9:30:10 AM CEST

Acq Method Set :

Gr0_0_MS_4min_0_45ml_K1_me_s



	RT	Area	Height (μV)	% Area
1	1.649	4046135	553696	96.35
2	2.835	62852	8048	1.50
3	3.991	90430	10634	2.15

A: 0.05% TFA in water

B: 0.05% TFA in acetonitrile

Gradient :

0.0 - 4 min 0 % B

4 - 5 min 5 - 95 % B

5 - 5.5 min 95 % B

5.5 - 6 min 95 - 0 % B

6 - 8 min 0 % B

0.45ml/min

Acquity UPLC HSS T3, 1.8μm, 2.1 x 150 mm column
column own temp. = 40 °C

2.5 Result of purity assessment

The overall purity is 96.35 % 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 PINEALON (1 mg) was dissolved in 1 mL of MilliQ water.
Injection: 6.0 µL

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3.5 Mass Spectra of PINEALON (PO-2025266)

Sample information

UPLC1 ZQ

Channel Description ACQUITY TUV ChA 214nm

Vial : 1:A,3 Vol. : 6.00 ul

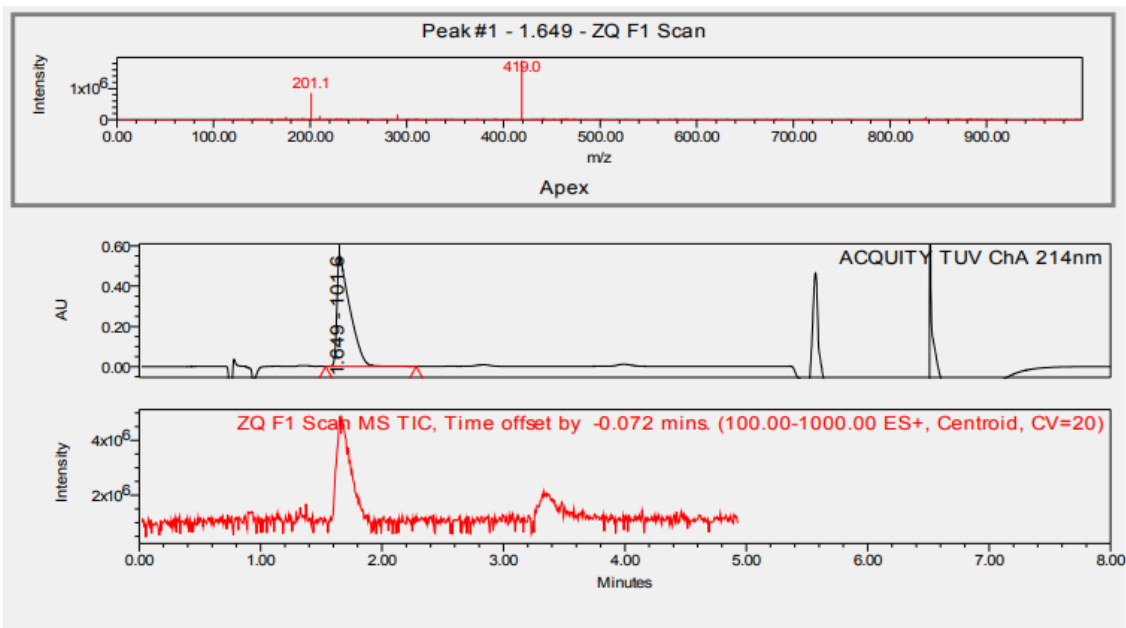
Sample: Pinealon (PO-2025266)

Date Acquired 6/27/2025 9:09:33 AM CEST

Date Processed 6/27/2025 9:29:05 AM CEST

Acq Method Set :

Gr0_0_MS_4min_0_45ml_K1_me_s



MS Result Table

	Name	RT	Base Peak (m/z)
1		1.649	101.55

UPLC conditions:

A: 0.05% TFA in water

B: 0.05% TFA in acetonitrile

Gradient :

0.0 - 4.0 min 0 % B

4.0 - 5.0 min 0 - 95 % B

5.0 - 5.5 min 95 % B

5.5 - 6.0 min 95 - 0 % B

6.0 - 16.0 min 0 % B

Theoretical values of m/z:

Peptide MW	[M+1H] ¹⁺	[M+2H] ²⁺	[M+3H] ³⁺	[M+4H] ⁴⁺	[M+5H] ⁵⁺	[M+6H] ⁶⁺
Calculated	419,2	210,1				
Found	419,0	201,1 (-H2O)	NA			

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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 μ 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:

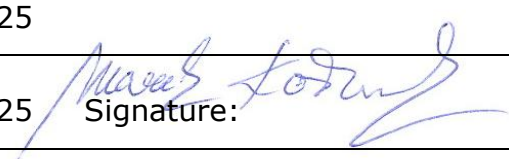
The sample PINEALON (Batch No. 2025266) was analyzed for peptide content, acetic acid content, UV purity, identity by MS and endotoxins.

Peptide content is 100.7 % (10.07 mg in 10 mg)

Purity is 96.35 % (UPLC at 214 nm).

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

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

ANALYSIS COMPLETED:	Date: 27.06.2025
Issued by QC:	Date: 27.06.2025  Signature:

Certificate Of Analysis



Client:**Particle Peptides**

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Sample Identification

Sample Name	Pinealon 10 mg	Batch Number	2025266	Date Published	2025-07-29 12:21
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Results for Lyo-0064

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-0064

	Method Specification	
Determination of bioburden of lyophilized samples		
<i>Document number</i> MIC_001_2025	<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-0064
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-0064
Filename: Bioburden-images-1.jpg

Responsibles



Mr. Ján Galbavý
Founder/Manager

Analysis results relate only to the samples tested.

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Protokol o skúške č. AR-25-KT-024525-01



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@etcee.eurofins.com, www.eurofins.sk	Názov a adresa zákazníka: PARTICLE s.r.o. Kolonáda 4490/18 984 01 Lučenec SLOVENSKO
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Dátum prevzatia vzorky: 25.06.2025 Dátum vykonania skúšky: 25.06.2025 - 02.07.2025 Dátum vystavenia protokolu: 02.07.2025

Informácie o vzorke: **104-2025-00025701**
Názov vzorky: Pinealon (PO-2025266)
Materiál: Peptidy

Fyzikálne a chemické skúšky

Parameter	Jednotka	Povolená hodnota	Výsledok merania	Neistota merania*	Princíp	Skúšobná metóda	H	SL	TS
Arzén (As)	mg/kg	max, 1,5	<0,03	-	ICP-MS	LS-PP-CH-85	V	TR	A
Kadmium (Cd)	mg/kg	max, 0,2	<0,10	-	ICP-MS	LS-PP-CH-85	V	TR	A
Olovo (Pb)	mg/kg	max, 0,5	<0,30	-	ICP-MS	LS-PP-CH-85	V	TR	A
Ortuť (Hg)	mg/kg	max, 0,3	<0,010	-	ICP-MS	LS-PP-CH-85	V	TR	A

Vysvetlivky: H - hodnotenie
V - vyhovuje
NE - nevyhovuje
(A) - akreditovaný odber
(SA) - akreditovaný odber vykonaný subdodávateľsky
ŠPP - 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 merania – odberu vzorky a analýzy - určená s koeficientom rozšírenia k=2 (s pravdepodobnosťou 95%). Ak vzorku odobral zákazník, neistota odberu nie je k dispozícii.
- rozšírená neistota uvedená v % vyjadruje neistotu z výsledku merania.
** - Prijateľná/y 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

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Výsledky analýz elektronicky validoval(i):

Ing. Michaela Ruttkayová
Odborný pracovník

Vyhotovil: Andrea Poduselová

Overenie platnosti dokumentu



Protokol o skúške schválil:

Ing. Michaela Ruttkayová
Odborný pracovník

