

ANALYTICAL CERTIFICATE

Page 1/10

Sample name	BPC-157
Batch No.	2024245
Sample No.	01
Sequence	Gly-Glu-Pro-Pro-Pro-Gly-Lys-Pro-Ala-Asp-Asp-Ala-Gly-Leu-Val
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

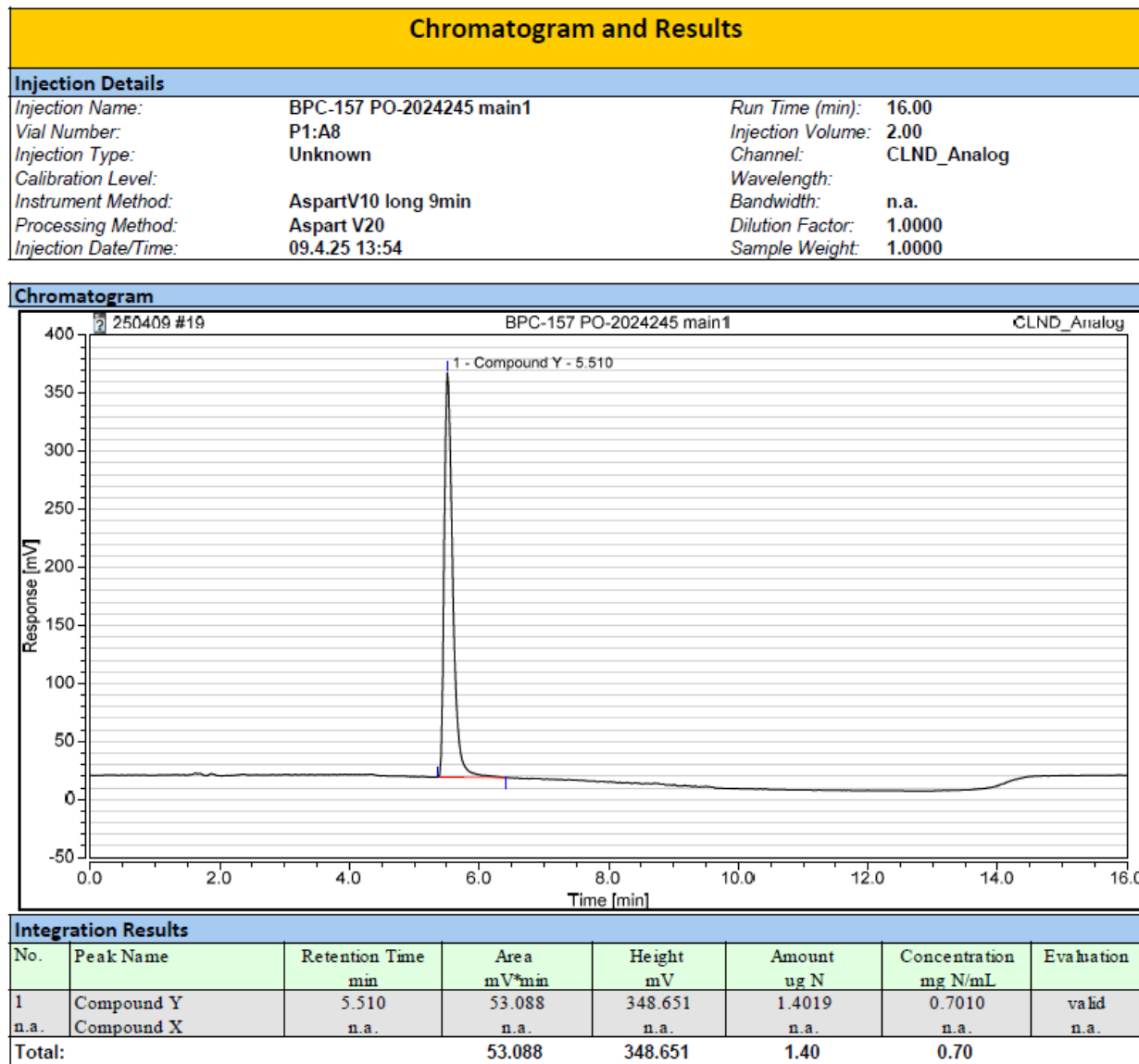
1.3 Sample preparation:

The whole amount of BPC-157 (5 mg) was dissolved in 1 mL of DMSO.
Injection: 2.0 μ L

ANALYTICAL CERTIFICATE

Page 2/10

1.4 Chromatograms and calibration curve:



ANALYTICAL CERTIFICATE

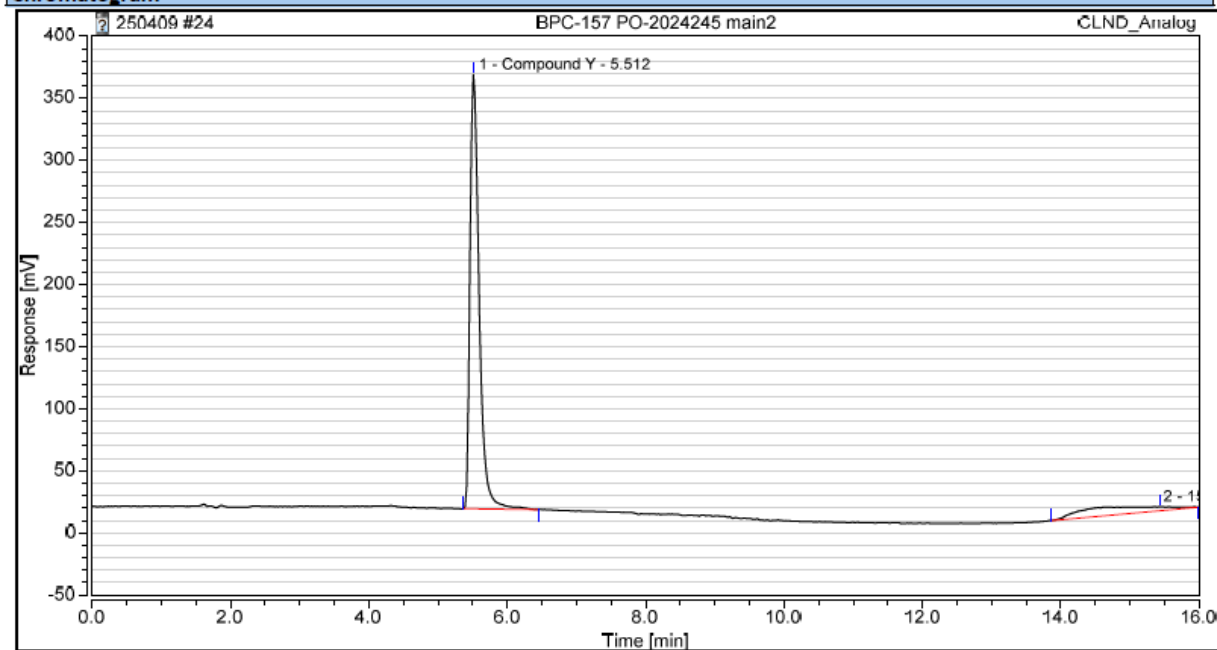
Page 3/10

Chromatogram and Results

Injection Details

Injection Name:	BPC-157 PO-2024245 main2	Run Time (min):	16.00
Vial Number:	P1:A8	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:	09.4.25 15:19	Sample Weight:	1.0000

Chromatogram

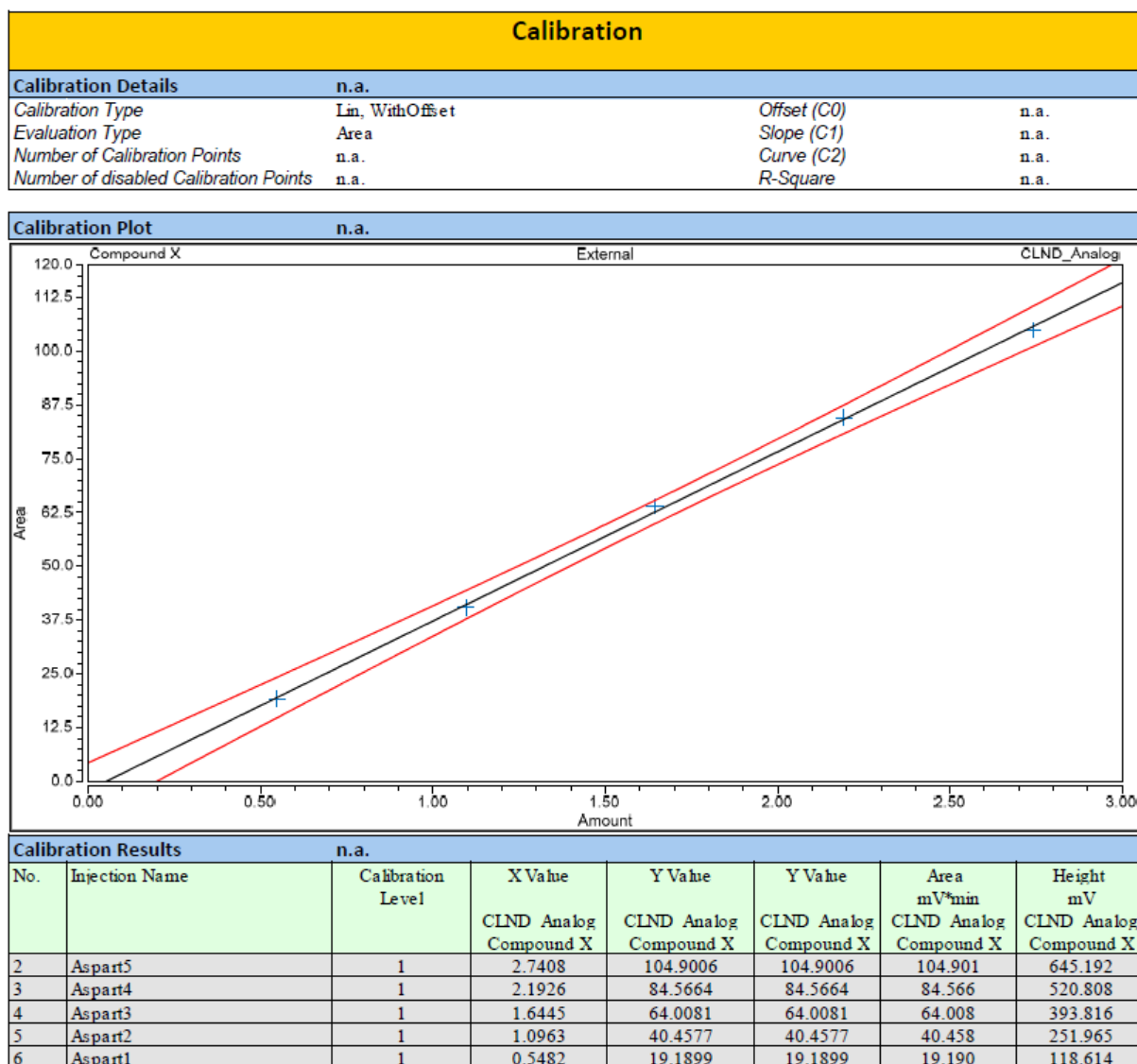


Integration Results

No.	Peak Name	Retention Time min	Area mV*min	Height mV	Amount ug N	Concentration mg N/mL	Evaluation
1	Compound Y	5.512	53.617	349.576	1.4154	0.7077	valid
n.a.	Compound X	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
2		15.427	8.215	3.256	n.a.	n.a.	n.a.
Total:			61.832	352.833	1.42	0.71	

ANALYTICAL CERTIFICATE

Page 4/10



ANALYTICAL CERTIFICATE

Page 5/10

1.5 Results:

NNC: BPC-157		Salt: AcOH	
MW (calculated) g/mol	N content (calculated) %	N conc. (measured) mg × N/ml	
1419,56	15,79	0,7044	
Theoretical Volume ml		Lyophilizate amount mg	
1,00		5,00	
Peptide concentration mg/ml		Quantified amount mg	
4,46	nmol/ml	4,5	nmol
	3142		3 142
Peptide content assay %			
89,2			

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	5	-	4,5	-	89,2 %

ANALYTICAL CERTIFICATE

Page 6/10

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:

Sample 1

An aliquote of BPC-157 (1 mg) was dissolved in 1 mL of 20% MeCN.

Injection: 4.0 µL

ANALYTICAL CERTIFICATE

Page 7/10

2.4 Chromatogram of BPC-157 (PO2024245)

Sample 1

Sample information

UPLC5

Sample: BPC-157 (PO-2024245)

Channel Description PDA Ch1 220nm@4.8nm

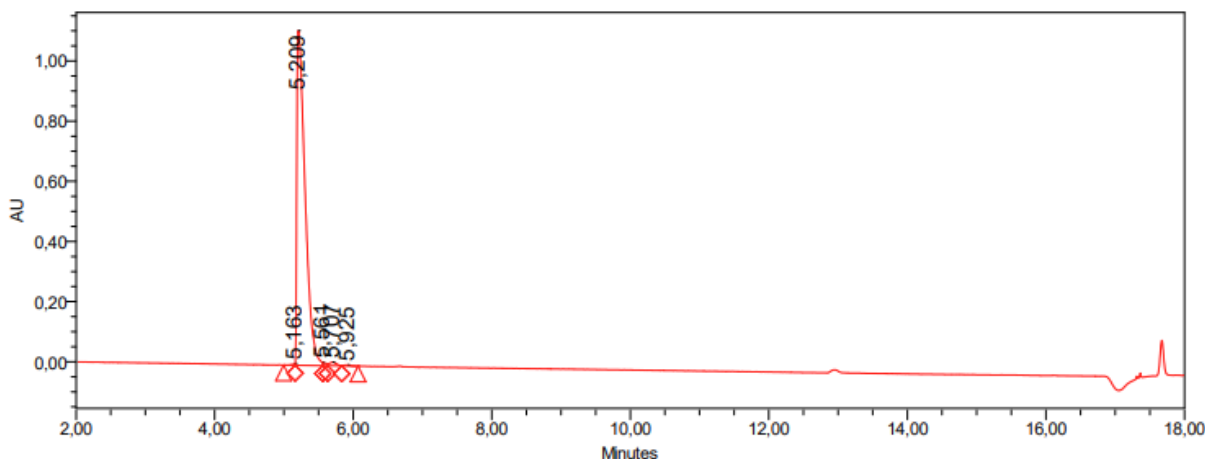
Date Acquired 09.04.2025 13:36:50 CEST

Vial : 1:F,1 Vol. : 4,00 ul

Date Processed 28.04.2025 10:14:15 CEST

Acq Method Set :

Gr_5_60_16min_40C_0_4_K1_me_s2



	RT	Area	Height (μV)	% Area
1	5,163	14437	5342	0,15
2	5,209	9180682	1113099	98,33
3	5,561	33107	10121	0,35
4	5,707	85809	12363	0,92
5	5,925	22770	3447	0,24

A: 0.05% TFA in water

B: 0.05% TFA in acetonitrile

Gradient : 5→ 60% B, 16min, 0.4ml/min

Acquity UPLC BEH130, 1.7μm, 2.1 x 150 mm column
column own temp. = 40 °C

2.5 Result of purity assessment

The overall purity is 98.33 % at 214 nm.

ANALYTICAL CERTIFICATE

Page 8/10

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 BPC-157 (1 mg) was dissolved in 1 mL of 20% MeCN.
Injection: 1.5 µL

ANALYTICAL CERTIFICATE

Page 9/10

3.5 Mass Spectra of BPC-157 (PO2024245)

Sample information

UPLC1_ZQ

Sample: BPC-157 (PO-2024245)

Channel Description ACQUITY TUV ChA 214nm

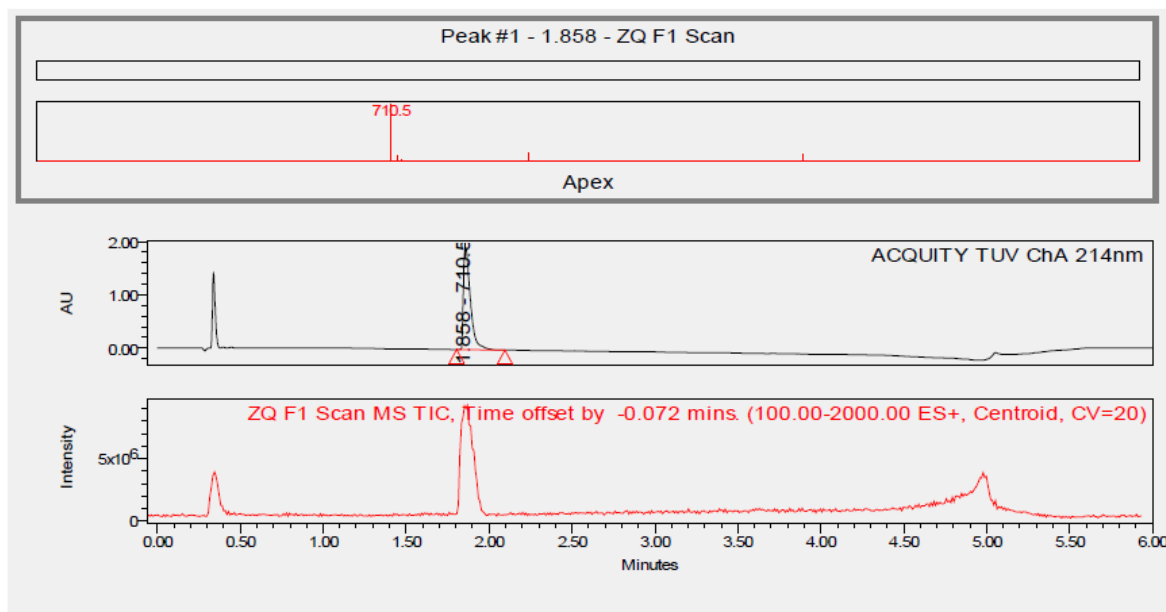
Date Acquired 4/9/2025 2:22:51 PM CEST

Vial : 1:A,3 Vol. : 1.50 ul

Date Processed 4/10/2025 8:35:17 AM CEST

Acq Method Set :

Gr5_60_MS_4min_0_45ml_K2_me_s



MS Result Table

	Name	RT	Base Peak (m/z)
1		1.858	710.48

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+2H] ²⁺	[M+3H] ³⁺	[M+4H] ⁴⁺	[M+5H] ⁵⁺	[M+6H] ⁶⁺	[M+7H] ⁷⁺
1419,6	710,8	474,2				
Found	710,5	NA				

ANALYTICAL CERTIFICATE

Page 10/10

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 µL 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:

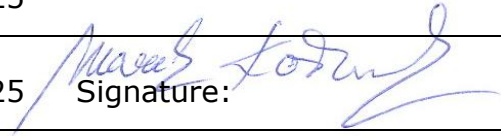
The sample BPC-157 (Batch No. 2024245) was analyzed for peptide content, UV purity, identity by MS and endotoxins.

Peptide content is 89.2 % (4.5 mg in 5 mg).

Purity is 98.33 % (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: 16.04.2025
Issued by QC:	Date: 17.04.2025 Signature: 

Analytical report AR-25-KT-012517-02



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: 07.04.2025 Date of Testing: 07.04.2025 - 10.04.2025

Issue date: 10.04.2025

Information about Sampling:

Sampler: customer

Sample information: 104-2025-00013277

Sample description: BPC-157 (PO-2024245)

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

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:

Zuzana Kubisová
Technical worker - registration

Worked out by: Zuzana Kubisová

Validity check of document

**Test Certificate approved by**Zuzana Kubisová
Technical worker - registration

Certificate Of Analysis



Client:**Particle Peptides**

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

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14000 Michle
Czechia
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Sample Identification

Sample Name	BPC-157 5 mg	Batch Number	2024245	Date Published	2025-07-29 12:19
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Results for Lyo-0063

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-0063

	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-0063
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-0063
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Responsibles



Mr. Ján Galbavý
Founder/Manager

Analysis results relate only to the samples tested.

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