

Certificate Of Analysis



Client:

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Sample Identification

Sample Name	GHRP-2 5 mg	Batch Number	2024224	Date Published	2025-11-21 15:01
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Results for Lyo-0156


Analysis of Peptide Identity, Content and Purity	Result	Unit	Uncertainty	Reporting Limit
GHRP-2 Assay Peptide Screening	4.76	mg	[± 0.02]	
GHRP-2 Identification by RT Peptide Screening	0.995		[± 0.005]	
GHRP-2 Identification by spectrum Peptide Screening	997		[± 20]	
GHRP-2 Purity Peptide Screening	99.6	%	[± 0.5]	

Bioburden	Result	Unit	Uncertainty	Reporting Limit
Total Aerobic Microbial Count USP <61>/Eur. Ph. 2.6.12. Plate Count Method	Not detected	CFU/g		>= 1000
Total Yeast and Mold Count USP <61>/Eur. Ph. 2.6.12. Plate Count Method	Not detected	CFU/g		>= 100

Endotoxin Analysis	Result	Unit	Uncertainty	Reporting Limit
Bacterial Endotoxin USP<85>/ Eur. Ph. 2.6.14. Bacterial Endotoxin Chromogenic Test	Detected but < 0.01	EU/mg		> 0.5

Attachments for Lyo-0156



	Method Specification		
Determination of identity, content and purity of GHRP-2			
<i>Document number</i> GHRP2_010_2025	<i>Superseded document</i> -	<i>Number of pages</i> 3	

1. Content Assesment

1.1. Instrumentation

Module	Name	Serial Number
System Controller	Shimadzu SCL-10ADvp	C21014112659
Degassing Unit	Shimadzu DGU-14A	NA
Pump A	Shimadzu LC-10ADvp	C20964130075
Pump B	Shimadzu LC-10ADvp	C20953770781
Autosampler	Shimadzu SIL-10ADvp	C21054109114
Colum Thermostat	Shimadzu CTO-10ACvp	C21033770144
Detector	Shimadzu SPD-10ADvp	C20994233588

1.2. Chromatographic conditions

Chromatographic conditions	
Eluent A	0.1% TFA in Water (HPLC, Gradient Grade)
Eluent B	0.1% TFA in Acetonitrile (HPLC, Gradient Grade)
Flow rate	0.4 mL/min
Program	Gradient elution
Injection volume	0.5 µL
Colum Temperature	60°C
Column	Phenomenex Biozen Peptide Polar C18, 150x2.1mm 3µm
Detection wavelenght	280nm

Gradient Program		
Time [min]	A [%]	B [%]
1	95	5
19	40	60
20	5	95
24	5	95
25	95	5
33	end	

1

Attachment for Lyo-0156

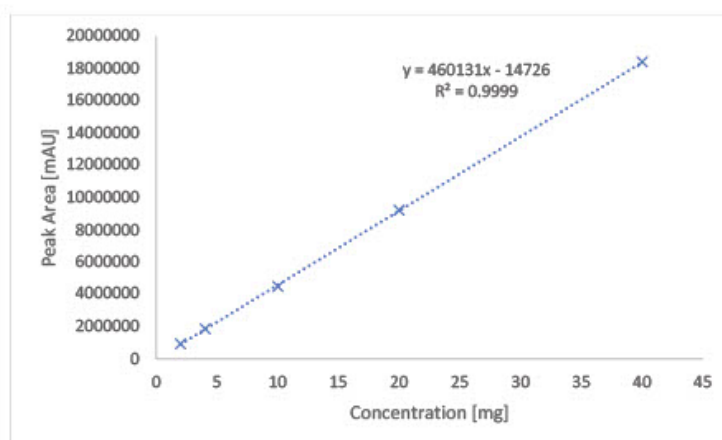
Filename: 1760291620605-c22be8db-67fa-436d-a1bf-ff188f4c778a_1.jpg

1.3. Sample preparation

Whole amount of container was dissolved in 2mL of water (HPLC, Gradient Grade). Aliquote part of 1 mL was dispensed into HPLC vial for analysis.

1.4. Calibration curve

Calibration curve detail	
Quantitative method	External Standard
Calibration Type	Linear
Number of calibration points	5
Force through Zero	Disabled
Weighting Method	None



2. Purity assessment

2.1 Instrumentation

Module	Name	Serial Number
System Controller	Shimadzu SCL-10ADvp	C21014112659
Degassing Unit	Shimadzu DGU-14A	NA
Pump A	Shimadzu LC-10ADvp	C20964130075
Pump B	Shimadzu LC-10ADvp	C20953770781
Autosampler	Shimadzu SIL-10ADvp	C21054109114
Column Thermostat	Shimadzu CTO-10ACvp	C21033770144
Detector	Shimadzu SPD-10ADvp	C20994233588

2.2 Chromatographic conditions

Chromatographic conditions	
Eluent A	0.1% TFA in Water (HPLC, Gradient Grade)
Eluent B	0.1% TFA in Acetonitrile (HPLC, Gradient Grade)
Flow rate	0.4 mL/min
Program	Gradient elution
Injection volume	0.5 µL
Column Temperature	60°C
Column	Phenomenex Biozen Peptide Polar C18, 150x2.1mm 3µm
Detection wavelength	214nm

Gradient Program		
Time [min]	A [%]	B [%]
1	95	5
19	40	60
20	5	95
24	5	95
25	95	5
33	end	

2.3 Sample preparation

Whole amount of container was dissolved in 2mL of water (HPLC, Gradient Grade). Aliquote part of 1 mL was dispensed into HPLC vial for analysis.

2.4 Purity assesment

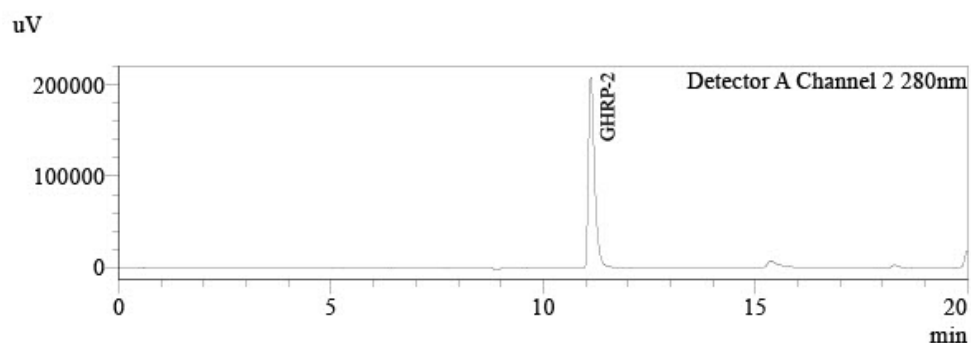
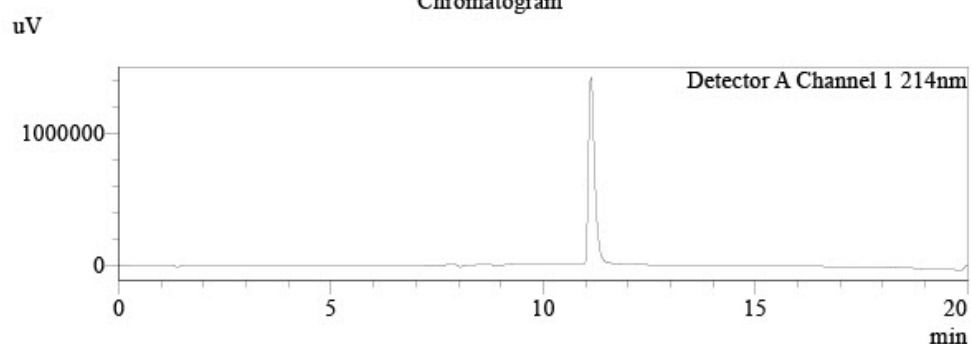
Purity of compound assesed by area normalization method, comparing area of each peak to sum of area of all peaks detected at wavelenght of 214 nm.

Analysis Report



Sample Information
 Injection Volume : 0,5
 Data File : LYO-0156-P01_002.lcd
 Method File : Peptide screening_V10.1_Group E.lcm
 Date Acquired : 15.11.2025 10:09:57

Chromatogram




Peak Table

Detector A Channel 1 214nm					
Peak#	Name	Ret. Time	Conc.	Unit	Area%
1		10.631	0.000		0.134
2		11.124	0.000		99.627
3		11.918	0.000		0.239
Total					100.000

Peak Table

Detector A Channel 2 280nm				
Peak#	Name	Ret. Time	Conc.	Unit
1	GHRP-2	11.122	4.763	mg
Total				

Attachment for Lyo-0156
 Filename: LYO-0156.jpg

	Method Specification		
Determination of bioburden of lyophilized samples			
Document number MIC_001_2025	Superseded document -	Number of pages 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. Process 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.

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Attachment for Lyo-0156
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:

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

$$CFU_{avg} = \text{average CFU counted form } n \text{ inoculations}$$
$$CFU_n = \text{CFU counted per inoculation}$$
$$n = \text{number of inoculations}$$

$$CFU \text{ per gram} = \frac{CFU_{avg}}{m_s} * DF$$
$$CFU_{avg} = \text{Average CFU counted from } n \text{ inoculations}$$
$$m_s = \text{mass of sample (mg)}$$
$$DF = \text{Dilution factor}$$

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

	Method Specification	
Determination of bacterial endotoxin content of lyophilized samples		
<i>Document number</i> ENDOTOX_002_2025	<i>Superseded document</i> ENDOTOX_001_2025	<i>Number of pages</i> 2

1. Chromgenic LAL Assay Determination of Bacterial Endotoxin content of sample

1.1. Instrumentation

- Pipette set 1-1000 µL
- Thermostatically controlled water bath
- UV VIS spectrometer (Shimadzu UV-1601)
- GenScript ToxinSensor Chromgenic LAL Endotoxin Assay kit

1.2. Chemicals

- LAL Reagent water (endotoxin free)
- Limulus Amoebocyte Lysate
- LAL Substrate
- Color Stabilizer #1
- Color Stabilizer #2
- Color Stabilizer #3
- 35% HCl (p.a.)

1.3. Sample preparation

1. Sample container was weighed prior to dissolution and measured weight was marked.
2. Sample was completely dissolved in its container by 2 mL of LAL Reagent water.
3. 100 µL of the sample was aliquoted for analysis.
4. After analysis container was emptied and dried.
5. Dry mass of container was measured and exact weight of dissolved content was determined as:

$$m_{dc} = m_{sample} - m_{container}$$

1.4. Toxin sensor Chromgenic LAL Endotoxin Assay kit preparation

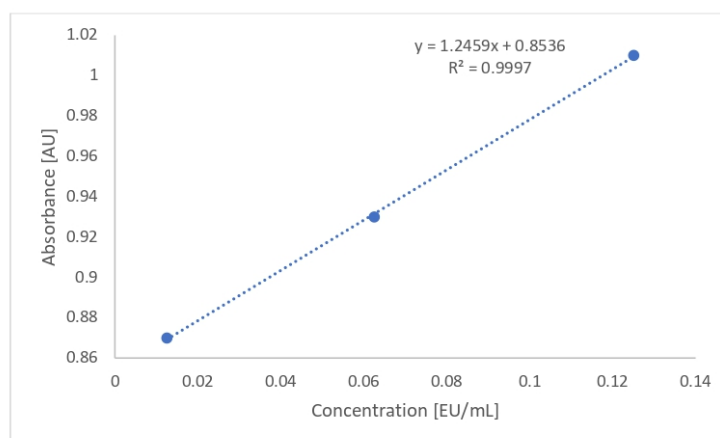
Procedures regarding preparation of reaction solutions possible to find in:

https://www.genscript.com/site2/document/5292_20080806231827.PDF

1.5. Measurement procedure

	Standards	Samples	Blank
Standards (mL)	0.1	-	-
Samples (mL)	-	0.1	-
LAL Reagent Water (mL)	-	-	0.1
LAL Solution (mL)	0.1	0.1	0.1
Mix well and incubate at 37°C for 27 min			
Substrate solution (mL)	0.1	0.1	0.1
Mix well and incubate at 37°C for 6 min			
Color Stabilizer #1 solution	0.5	0.5	0.5
Color Stabilizer #2 solution	0.5	0.5	0.5
Color Stabilizer #3 solution	0.5	0.5	0.5
Mix well and read the absorbance at 545nm			

1.6. Calibration curve



1.7. Calculation of endotoxin content

Endotoxin content of the sample was calculated from the calibration curve as:

$$Endotox[EU/mg] = \frac{\left(\frac{ABS_{sample}}{S_{calib}}\right) * 20}{m_{sample}}$$

ABS_{sample} = Measured absorbance of sample

S_{calib} = Slope of calibration curve

m_{sample} = real measured mass of sample

20 = dilution factor of measured sample



Mr. Ján Galbavý
Founder/Manager

Analysis results relate only to the samples tested.

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Analytical report AR-25-KT-001273-02



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: 16.01.2025 Date of Testing: 16.01.2025 - 20.01.2025

Issue date: 20.01.2025

Information about Sampling:

Sampler: customer

Sample information: 104-2025-00001478

Sample description: GHPR-2 (PO-2024224)

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

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:

RNDr. Hana Benkovičová
Deputy Head of Laboratory Turčianske Teplice

Worked out by: Zuzana Kubisová

Validity check of document

**Test Certificate approved by**

RNDr. Hana Benkovičová
Deputy Head of Laboratory Turčianske Teplice

