

ANALYTICAL CERTIFICATE

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Sample name	ModGRF 1-29
Batch No.	2024198
Sample No.	NA
Sequence	Tyr-D-Ala-Asp-Ala-Ile-Phe-Thr-Gln-Ser-Tyr-Arg-Lys-Val-Leu-Ala-Gln-Leu-Ser-Ala-Arg-Lys-Leu-Leu-Gln-Asp-Ile-Leu-Ser-Arg-NH ₂
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 1120 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 ModGRF 1-29 (5 mg) was dissolved in 1 mL of DMSO.
Injection: 2 μ L

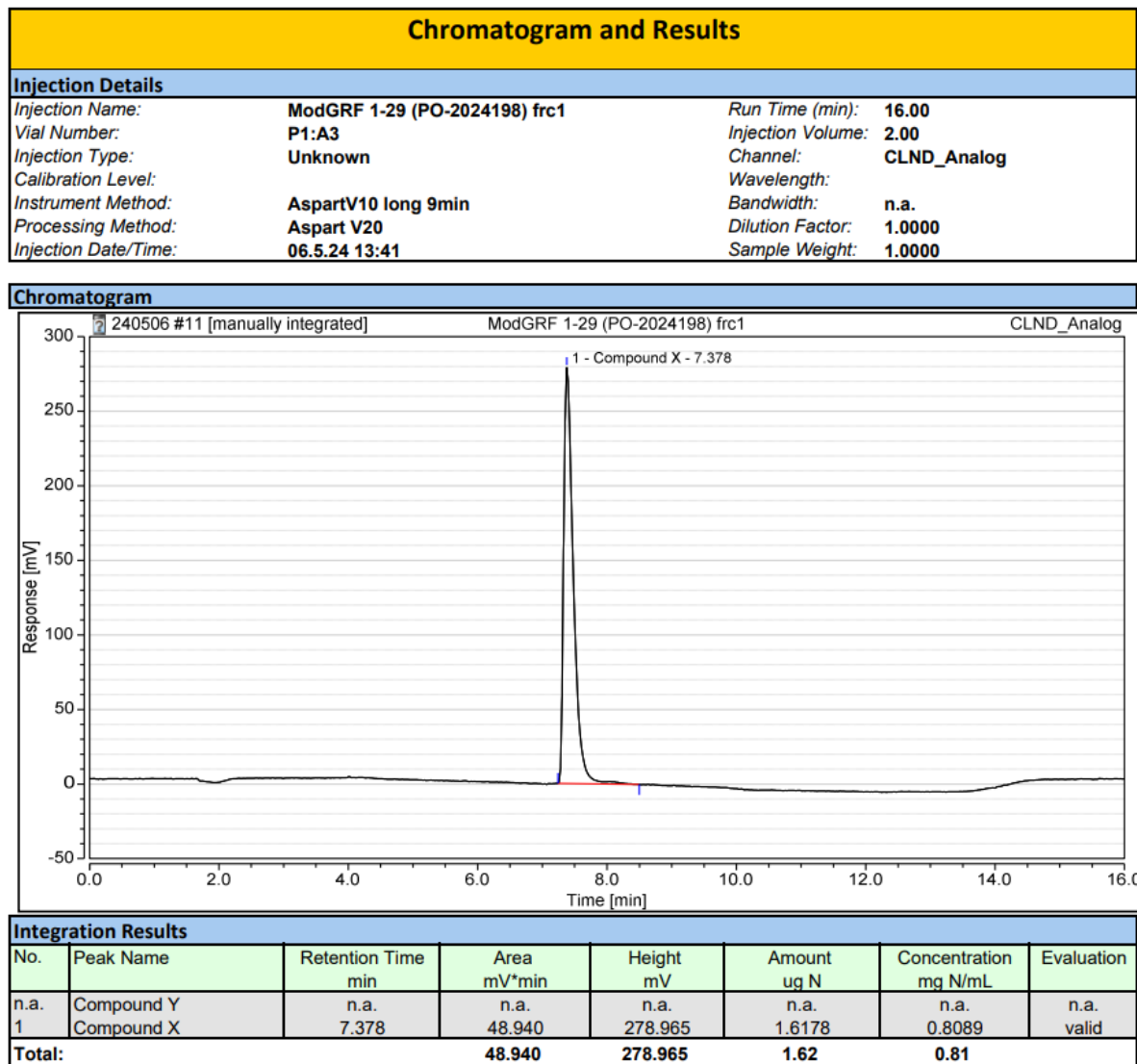
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1.4 Chromatograms and calibration curve:

Instrument:CLND-2 Sequence:240506

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Instrument:CLND-2 Sequence:240506

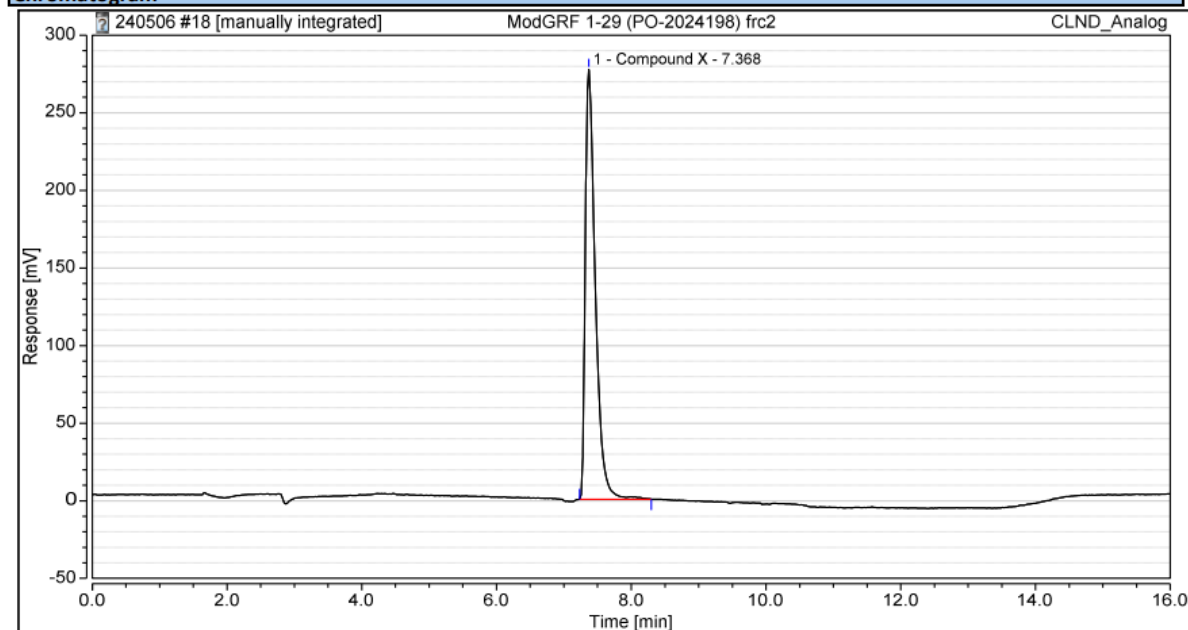
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Chromatogram and Results

Injection Details

Injection Name:	ModGRF 1-29 (PO-2024198) frc2	Run Time (min):	16.00
Vial Number:	P1:A3	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:	06.5.24 16:02	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
n.a.	Compound Y	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
1	Compound X	7.368	48.023	276.948	1.5902	0.7951	valid
Total:			48.023	276.948	1.59	0.80	

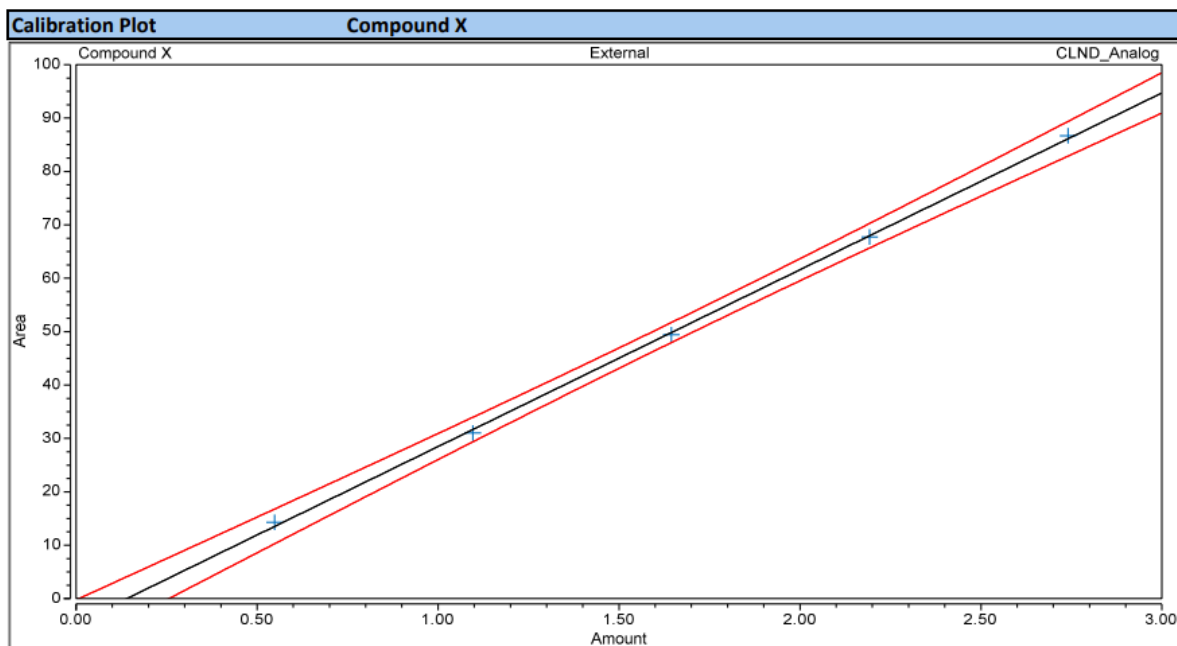
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Instrument:CLND-2 Sequence:240506

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Calibration			
Calibration Details		Compound X	
Calibration Type	Lin, WithOffset	Offset (C0)	-4.6400
Evaluation Type	Area	Slope (C1)	33.1182
Number of Calibration Points	5	Curve (C2)	0.0000
Number of disabled Calibration Points	0	R-Square	0.9995



Calibration Results		Compound X					
No.	Injection Name	Calibration Level	X Value	Y Value	Y Value	Area	Height
			CLND_Analog Compound X	CLND_Analog Compound X	CLND_Analog Compound X	mV*min CLND_Analog Compound X	mV CLND_Analog Compound X
2	Aspart5	1	2.7408	86.6752	86.6752	86.675	496.135
3	Aspart4	1	2.1926	67.7452	67.7452	67.745	390.701
4	Aspart3	1	1.6445	49.4061	49.4061	49.406	285.333
5	Aspart2	1	1.0963	31.0037	31.0037	31.004	178.459
6	Aspart1	1	0.5482	14.2770	14.2770	14.277	82.006

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1.4 Results:

NNC: ModGRF 1-29 (PO2024:		Salt:	0
MW (calculated) g/mol	N content (calculated) %	N conc. (measured) mg × N/ml	
3367,95	18,3	0,8020	
Theoretical Volume ml		Lyophilizate amount mg	
1,00		5,00	
Peptide concentration mg/ml nmol/ml		Quantified amount mg nmol	
4,38 1301		4,4 1 301	
Peptide content assay %			
87,7			

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.
ModGRF 1-29	5	NA	4,4	NA	87.7 %

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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 4 min, according to chromatogram results
Column: Waters Acquity BEH, C-18, 1.7µm, 2.1mm x 50mm
 Part No 186002353

2.3 Sample preparation:

The whole amount of ModGRF 1-29 (5 mg) was dissolved in 1 mL of DMSO.
Injection: 0.2 µL

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2.4 Chromatogram of ModGRF 1-29 (PO-2024198)

Sample information

UPLC2

Channel Description ACQUITY TUV ChA 214nm

Vial : 1:C,3 Vol. : 0.20 ul

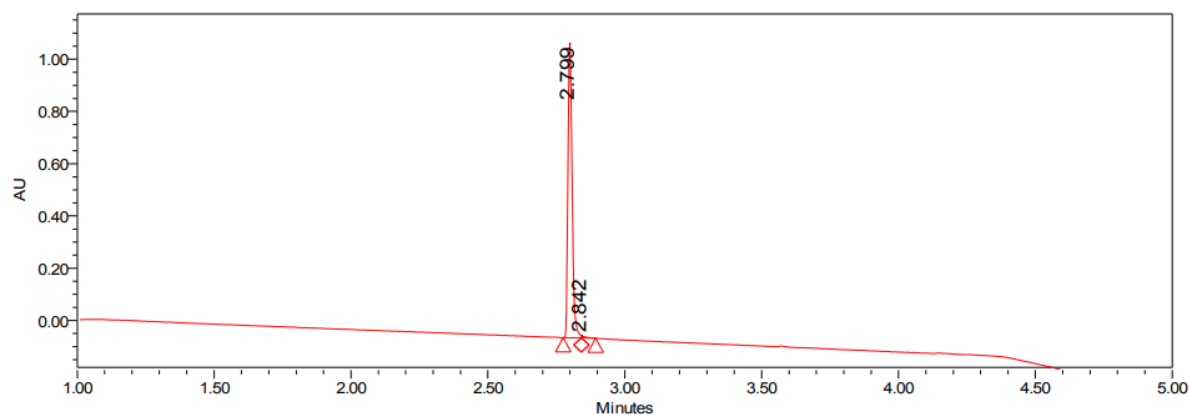
Sample: ModGRF 1-29 (PO-2024198)

Date Acquired 5/7/2024 1:57:00 PM CEST

Date Processed 5/7/2024 4:41:50 PM CEST

Acq Method Set :

Gr_5_60_4mi_40C_0_45_K2_met_s



	RT	Area	Height (μV)	% Area
1	2.799	1191222	1134064	99.26
2	2.842	8912	9237	0.74

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 99.26 % at 214 nm.

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CONCLUSION:

The sample Modified GRF 1-29 (Batch No. 2024198) was analyzed for peptide content and UV purity.

Peptide content is 87.7 % (4.4 mg in 5 mg)

Purity is 99.26 % (UPLC at 214 nm).

ANALYSIS COMPLETED:	Date: 07.05.2024
Issued by QC:	Date: 09.05.2024 Signature: 

As of 06-May-2024 09:54 (UTC+02:00) this information pertains to all reports for Eurofins Batch Number: W124AA1601.

Testing for this Batch was performed under the following regulatory guidelines: GMP Commercial.

Sample Number	Sample Description	Included In This Reporting Group	Report Version	Report Revision Log
W124AA1601-1	ModGRF 1-29 (PO-2024198) 5 mg glass vials; BPT Received Date 29-Apr-2024	✓	1	Original Report - Analytical Report ABK05529

Contracted Testing Facility	Testing Performed
<p>Eurofins BioPharma Product Testing Slovakia s.r.o. (Bratislava) Kollárovo nám. 9 Bratislava, 811 07 SK CSPharmaSK@eurofins.sk www.eurofins.sk</p> <p>Questions about this report should be directed to your project manager or the general email listed above.</p>	
Other Eurofins BPT Testing Facilities	Testing Performed
<p>Eurofins BioPharma Product Testing Slovakia s.r.o. (Piešťany) Mudronova 25 Piešťany, 921 01 SK</p>	<p>Ph Eur Bacterial endotoxins Total Aerobic Microbial Count - Pour Plate Total Yeast and Mold Count-Pour Plate</p>

Prepared For	Reports Provided To
<p>PARTICLE s.r.o. Kolonáda 4490/18 Lučenec, 984 01 SK</p> <p>Client Account Number: A01677317RLW Eurofins Quote Number: K8MWPH24000401</p>	<p>Admin (Primary Reporting Contact) admin@particlepeptides.com</p>

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

Client Account Number: A01677317RLW
Eurofins Quote Number: K8MWPB24000401

Eurofins Sample Number W124AA1601-1			
Original Received Date:		29-Apr-2024	
Description:		ModGRF 1-29 (PO-2024198) 5 mg glass vials	
Analysis	Specification	Result	Unit
Total Aerobic Microbial Count - Pour Plate	----	0	CFU/vial
Method: Current Ph Eur (2.6.12); Current USP/NF <61>; Current JP (English) <4.05 I>; Current BP Appendix XVI Analysis Date: 29-Apr-2024 to 04-May-2024			
Total Yeast and Mold Count-Pour Plate	----	0	CFU/vial
Method: Current Ph Eur (2.6.12); Current USP/NF <61>; Current JP (English) <4.05 I>; Current BP Appendix XVI Analysis Date: 29-Apr-2024 to 04-May-2024			
Ph Eur Bacterial endotoxins	Max. 0.5	<0.5	IU/mg
Method: Current Ph Eur (2.6.14, Method A) Analysis Date: 02-May-2024 to 02-May-2024			
Sample Compliance Assessment			
W124AA1601-1 meets the requirement(s) for all listed test(s) where specifications were applied.			

Supplemental Information

Compliance statement was created according to comparison of test results in this report with the limits stated in product specification. Comparison refers to all of the tested parameters.

Laboratory is working in GMP system, is holder of Certificate of GMP compliance of a manufacturer No. SK/018V/2022 for physical-chemical testing and No. SK/019V/2022 for microbiological testing.

Tests are performed in compliance with GMP requirements for quality control laboratories. Tests are performed according to actual version of specification, unless the customer requires otherwise.

Laboratory is not responsible for the information provided by the customer, which can affect the validity of the results.

Test results can be claimed for 14 days from sending the results to the customer. Sample rests are stored 14 days from sending results to the customer and then are disposed according to Testing laboratory's regulations.

Eurofins BPT Testing Facility	Test
Eurofins BioPharma Product Testing Slovakia s.r.o. (Piešťany) Mudronova 25 Piešťany, 921 01 SK	Ph Eur Bacterial endotoxins Total Aerobic Microbial Count - Pour Plate Total Yeast and Mold Count-Pour Plate

Contracted Company: Eurofins BioPharma Product Testing Slovakia s.r.o. (Bratislava)

Kollárovo nám. 9, Bratislava, 811 07 SK
CSPharmaSK@eurofins.sk

Questions about this report should be directed to your project manager or the general email listed above.

Reviewed and electronically signed for Technical Supervisor Approval by
Vojtech Licko, ASM QC
for Eurofins BioPharma Product Testing Slovakia s.r.o. , on 06-May-2024 09:04:53 UTC+02:00
Reviewed and electronically signed for Quality Assurance Release by
Andrea Vargova, QA/QC / Head of Laboratory
for Eurofins BioPharma Product Testing Slovakia s.r.o. , on 06-May-2024 09:54:07 UTC+02:00