ANALYTICAL CERTIFICATE

Sample name	**Tesamorelin**
Batch No.	**2024203**
Sample No.	**01**
Sequence	Trans-3-Hexenoyl-Tyr-Ala-Asp-Ala-Ile-Phe-Thr-Asn-Ser-Tyr-Arg-Lys-Val-Leu-Gly-Gln-Leu-Ser-Ala-Arg-Lys-Leu-Leu-Gln-Asp-Ile-Met-Ser-Arg-Gln-Gln-Gly-Glu-Ser-Asn-Gln-Glu-Arg-Gly-Ala-Arg-Ala-Arg-Leu-NH2
Manufacturing date	**NA**
Submitter of analytical request	Adria Peptides d.o.o.

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 5µ C4-BIO 300 A, 4.6 x 100 mm
Serial No 221258

1.3 Sample preparation:

The whole amount of Tesamorelin (10mg) was dissolved in 1 mL of DMSO.
Injection: 2.0 µL

ANALYTICAL CERTIFICATE

1.4 Chromatograms and calibration curve:

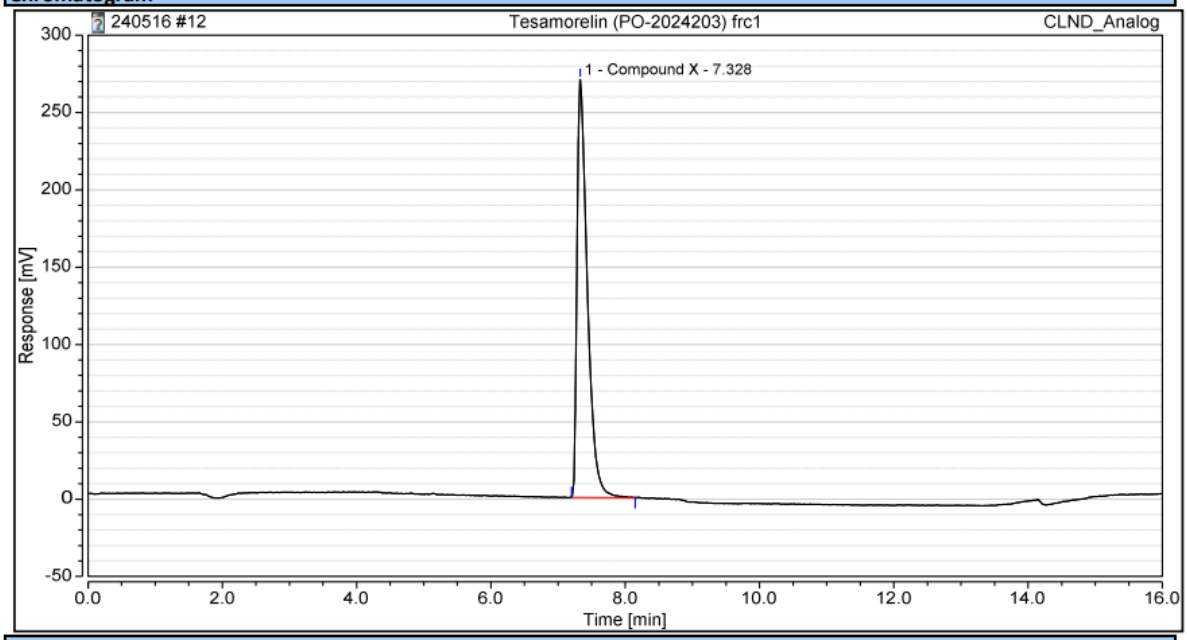
Instrument:CLND-2 Sequence:240516 Page 1 of 2

Chromatogram and Results

Injection Details

Injection Name:	**Tesamorelin (PO-2024203) frc1**	*Run Time (min):*	**16.00**
Vial Number:	**P1:C2**	*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:	**16.5.24 14:38**	*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	7.328	48.061	270.161	1.6457	0.8228	valid
Total:			**48.061**	**270.161**	**1.65**	**0.82**	

ANALYTICAL CERTIFICATE

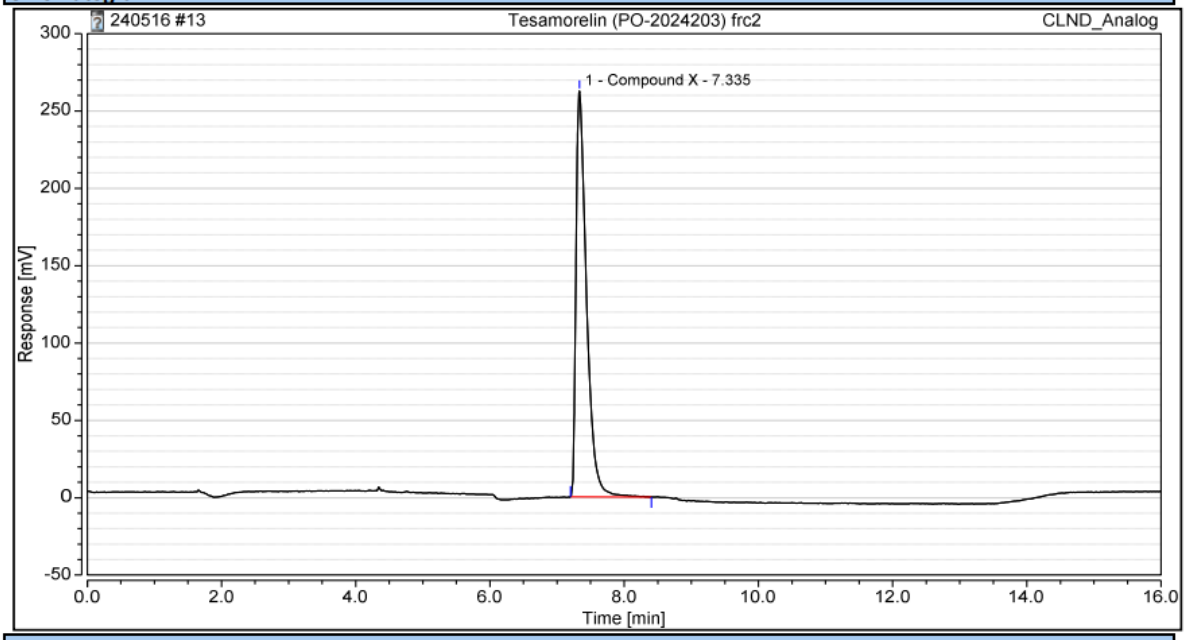
Instrument:CLND-2 Sequence:240516

Chromatogram and Results

Injection Details

Injection Name:	**Tesamorelin (PO-2024203) frc2**	*Run Time (min):*	**16.00**
Vial Number:	**P1:C2**	*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:	**16.5.24 15:08**	*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	7.335	47.564	262.366	1.6300	0.8150	valid
Total:			**47.564**	**262.366**	**1.63**	**0.81**	

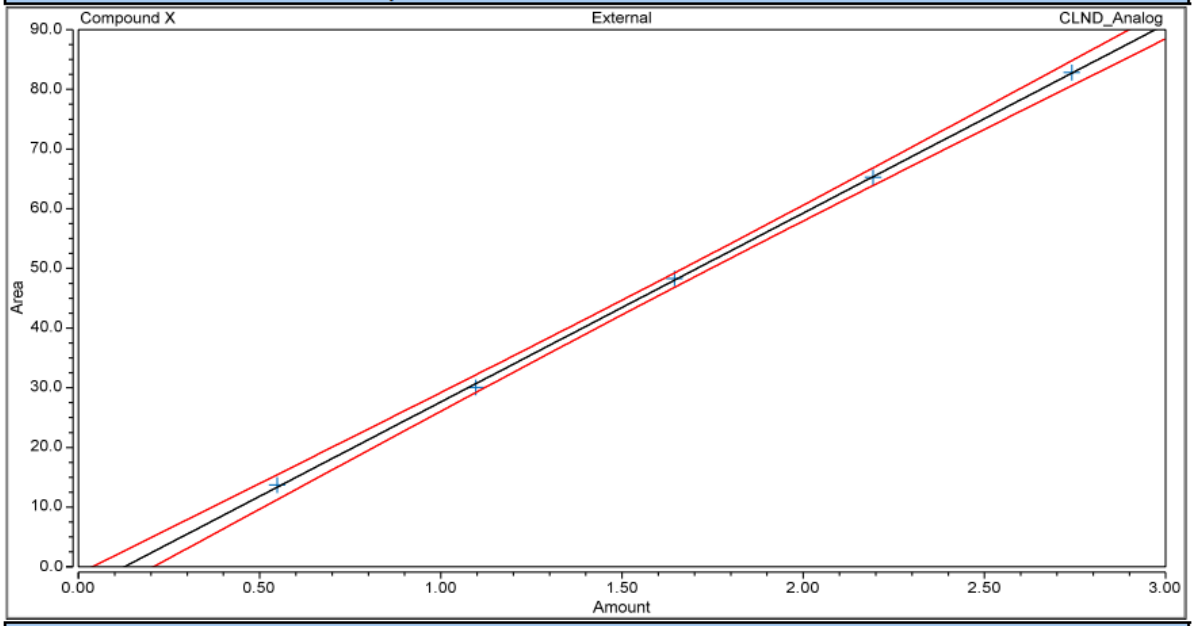
ANALYTICAL CERTIFICATE

Instrument:CLND-2 Sequence:240516

Calibration

Calibration Details	Compound X		
Calibration Type	Lin, WithOffset	*Offset (C0)*	-4.0058
Evaluation Type	Area	*Slope (C1)*	31.6385
Number of Calibration Points	5	*Curve (C2)*	0.0000
Number of disabled Calibration Points	0	*R-Square*	0.9998

Calibration Plot **Compound X**



Calibration Results **Compound X**

No.	Injection Name	Calibration Level	X Value CLND_Analog Compound X	Y Value CLND_Analog Compound X	Y Value CLND_Analog Compound X	Area mV*min CLND_Analog Compound X	Height mV CLND_Analog Compound X
2	Aspart5	1	2.7408	82.8118	82.8118	82.812	474.666
3	Aspart4	1	2.1926	65.2513	65.2513	65.251	397.477
4	Aspart3	1	1.6445	48.3019	48.3019	48.302	287.720
5	Aspart2	1	1.0963	30.0439	30.0439	30.044	180.036
6	Aspart1	1	0.5482	13.7022	13.7022	13.702	82.075

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1.4 Results:

NNC: Tesamorelin (PO-20242 Salt: 0

MW (calculated) g/mol	N content (calculated) %	N conc. (measured) mg × N/ml
5135,86	19,64	0,8189

Theoretical Volume ml	Lyophilizate amount mg
1,00	5,00

Peptide concentration mg/ml	Peptide concentration nmol/ml	Quantified amount mg	Quantified amount nmol
4,17	812	4,2	812

Peptide content assay %
83,4

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.
Tesamorelin	5	NA	**4.2**	NA	83,4 %

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:	0.45 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:

An aliquote of Tesamorelin (5 mg) was dissolved in 1 mL of 30% MeCN.

Injection: 2.0 µL

2.4 Chromatogram of Tesamorelin (PO-2024203)

Sample information

UPLC2

Channel Description ACQUITY TUV ChA 214nm

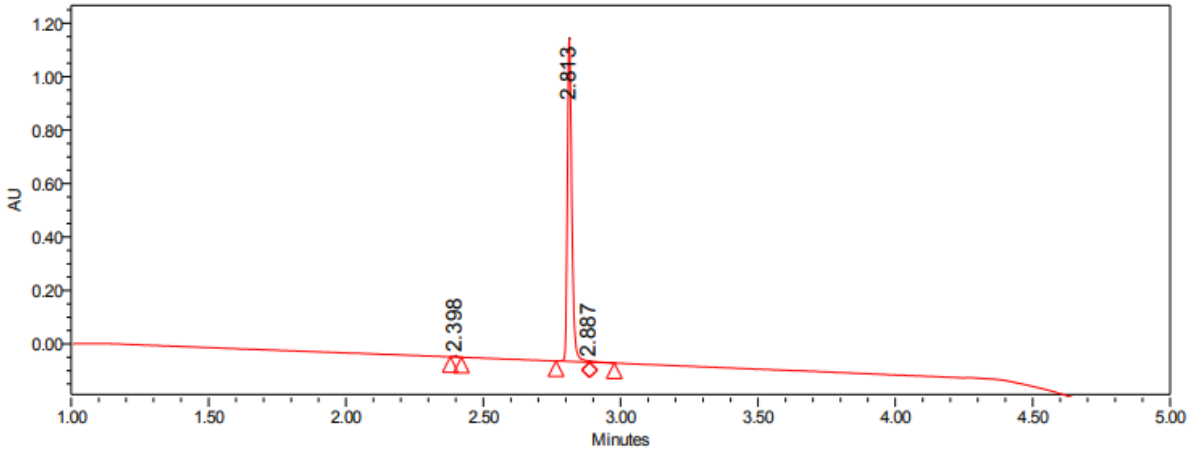
Vial : 1:A,2 Vol. : 2.00 ul

Sample: Tesamorelin (PO-2024203]

Date Acquired 5/23/2024 1:07:26 PM CEST

Date Processed 5/23/2024 2:20:21 PM CEST

Acq Method Set :
Gr_5_60_4mi_40C_0_45_K2_met_s



	RT	Area	Height (µV)	% Area
1	2.398	4705	4753	0.34
2	2.813	1371751	1210649	99.18
3	2.887	6646	3764	0.48

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, 1.7um, 2.1 x 50 mm column
column own temp. = 40 °C

2.5 Result of purity assessment

The overall purity is 99.18 % at 214 nm.

ANALYTICAL CERTIFICATE

CONCLUSION:
The sample Tesamorelin (Batch No. 2024203) was analyzed for peptide content and UV purity.

Peptide content is 83.4 % (4.2 mg in 5 mg).
Purity is 99.18 % (UPLC at 214 nm).

ANALYSIS COMPLETED:	Date: 23.05.2024
Issued by QC:	Date: 23.05.2024 Signature:

Analytical report AR-24-KT-043634-02

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: 22.11.2024 **Date of Testing**: 22.11.2024 - 26.11.2024 **Issue date:** 03.12.2024

Information about Sampling:
Sampler: customer

Sample information: **104-2024-00048100**
Sample description: Tesamorelin (PO-2024203)
Material: Peptidy

Physical and chemical tests

Parameter	Unit	Allowed Value	Measured Value	Uncertainty of measurement*	Method	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

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

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 eith 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: Andrea Podušelová

Validity check of document

Eurofins Environment Testing Slovakia s.r.o. - 1 - AKREDITOVANÉ SKÚŠOBNÉ LABORATÓRIUM SNAS č. S-406

Test Certificate approved by

Michaela Ruttkayová
Specialist worker

As of 15-May-2024 17:19 (UTC+02:00) this information pertains to all reports for Eurofins Batch Number: W124AA1816.
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
W124AA1816-1	Tesamorelin (PO-2024203) 5 mg glass vials; BPT Received Date 29-Apr-2024	✓	1	Original Report - Analytical Report ABK24266

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

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

eurofins | BioPharma Product Testing

Certificate of Analysis

Analytical Report: ABK24266
Eurofins Sample Number: W124AA1816-1
Version: 1

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

Client Account Number: A01677317RLW
Eurofins Quote Number: K8MWPH24000401

Eurofins Sample Number W124AA1816-1

Original Received Date: 29-Apr-2024
Description: Tesamorelin (PO-2024203)
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: 10-May-2024 to 15-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: 10-May-2024 to 15-May-2024			
Ph Eur Bacterial endotoxins	Max. 0.5	<0.5	IU/mg
Method: Current Ph Eur (2.6.14, Method A) Analysis Date: 14-May-2024 to 14-May-2024			

Sample Compliance Assessment

W124AA1816-1 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 Piešť'any, 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 15-May-2024 11:01:11 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 15-May-2024 17:18:55 UTC+02:00