ANALYTICAL CERTIFICATE

Sample name	**EPITHALON**
Batch No.	**2023179**
Sample No.	**01**
Specification	**NA**
Manufacturing date	**NA**
Submitter of analytical request	**UAB Nauja oda eshop, Lithuania**

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 EPITHALON (5 mg) was dissolved in 1 mL of H_2O.
Injection: 2.0 µL

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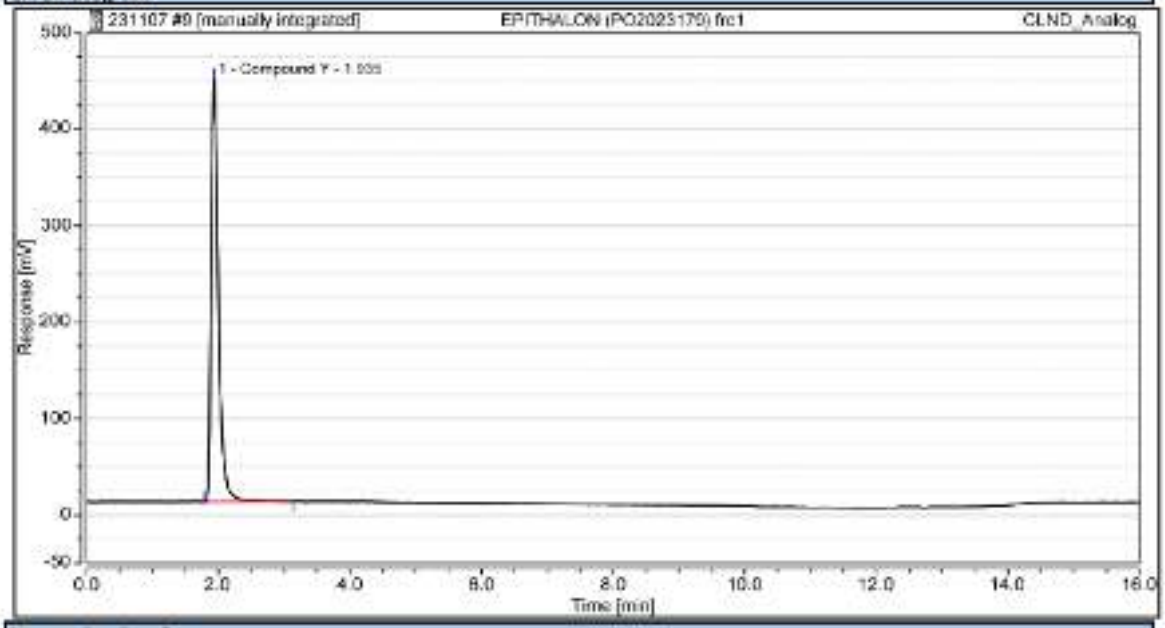
1.4 Chromatograms and calibration curve:

Chromatogram and Results

Injection Details

Injection Name:	**EPITHALON (PO2023179) frc1**	*Run Time (min):*	**16.00**
Vial Number:	**P1:A6**	*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:	**07.11.23 09:39**	*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	1.935	55.348	438.622	1.5685	0.7848	valid
n.a.	Compound X	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Total:			**55.348**	**438.622**	**1.57**	**0.78**	

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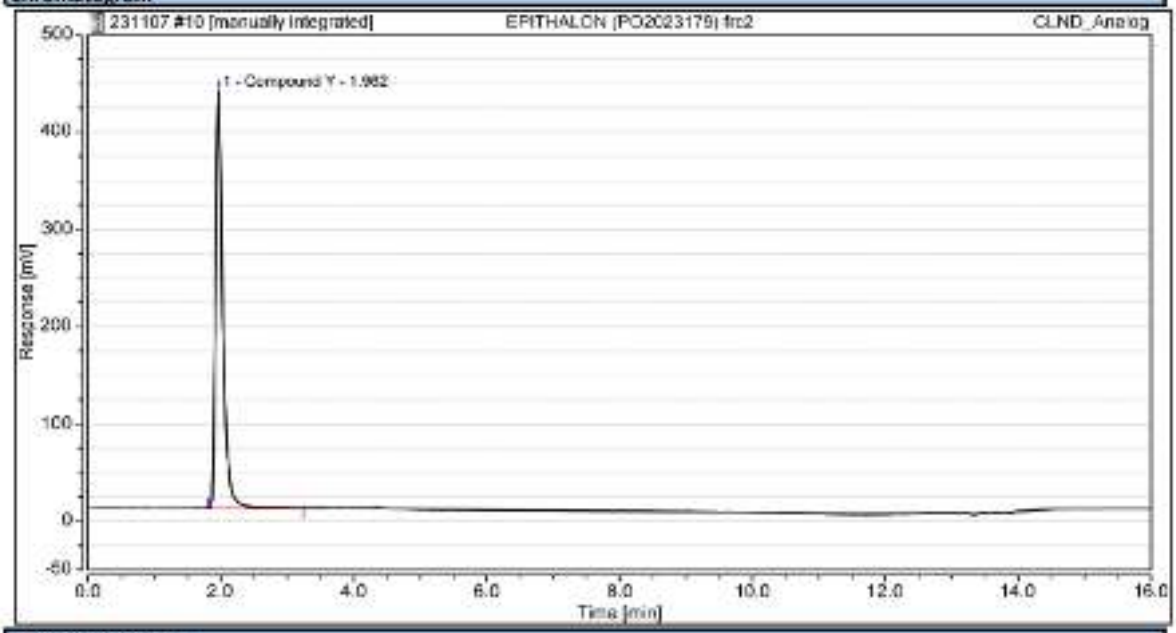
Instrument:CLND-2 Sequence:231107 Page 1 of 2

Chromatogram and Results

Injection Details

Injection Name:	**EPITHALON (PO2023179) frc2**	*Run Time (mn):*	**16.00**
Vial Number:	**P1:A6**	*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:	**07.11.23 10:27**	*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	1.962	54.197	428.969	1.5387	0.7694	valid
n.a.	Compound X	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Total:			**54.197**	**428.969**	**1.54**	**0.77**	

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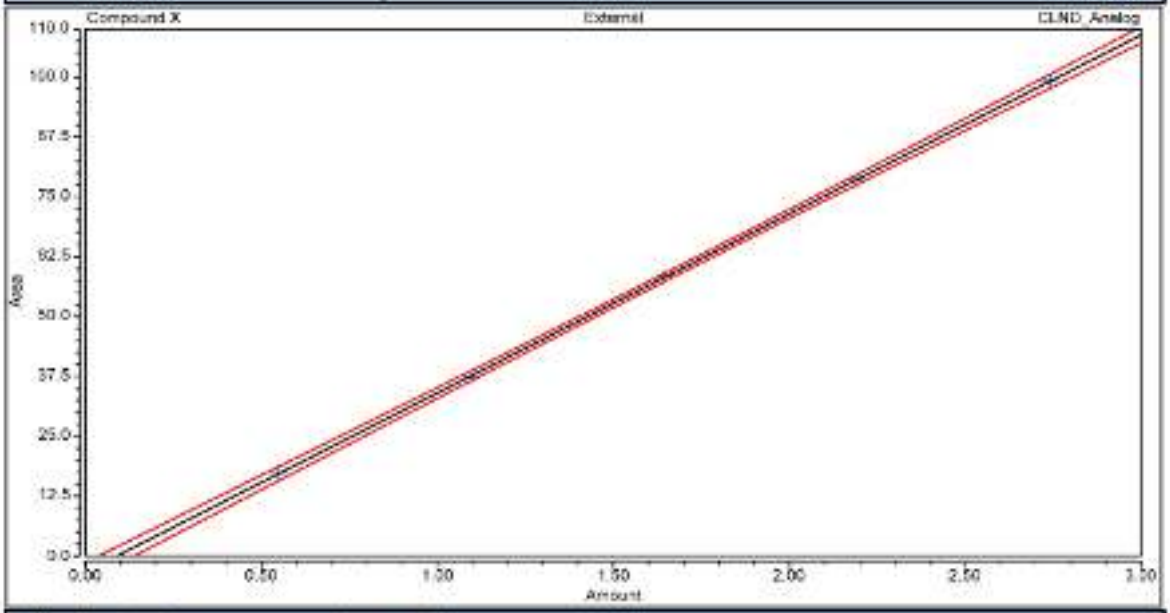
Calibration

Calibration Details	Compound X		
Calibration Type	Lin, WithOffset	Offset (C0)	-3.3293
Evaluation Type	Area	Slope (C1)	37.3858
Number of Calibration Points	5	Curve (C2)	0.0000
Number of disabled Calibration Points	0	R-Square	0.9999

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	2.7406	99.1951	99.1951	99.195	586.039
3	Aspart4	1	2.1926	78.5024	78.5024	78.502	466.705
4	Aspart3	1	1.6445	58.4463	58.4463	58.446	350.654
5	Aspart2	1	1.0963	37.2486	37.2486	37.250	225.527
6	Aspart1	1	0.5482	17.3561	17.3561	17.356	106.285

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1.4 Results:

NNC: EPITHALON (PO-202317 Salt: AcOH

MW (calculated) g/mol	N content (calculated) %	N conc. (measured) mg × N/ml
390,35	**14,35**	**0,7771**

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

Peptide concentration		Quantified amount	
mg/ml	nmol/ml	mg	nmol
5,42	**13873**	**5,4**	**13 873**

Peptide content assay %
108,3

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.
EPITHALON	5	7,4	**5,42**	NA	108,3 %

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 0% B to 20% B in 16 min, according to chromatogram results
Column:	Waters Acquity BEH, C-18, 1.7µm, 2.1mm x 150mm
	Part No 186002353

2.3 Sample preparation:

The whole amount of EPITHALON (5 mg) was dissolved in 1 mL of H_2O. An aliquote was diluted 5 times by water.

Injection: 2.5 µL

2.4 Chromatogram of EPITHALON (PO2023179)

Sample information

UPLC2 **Sample: EPITHALON (PO2023179)**

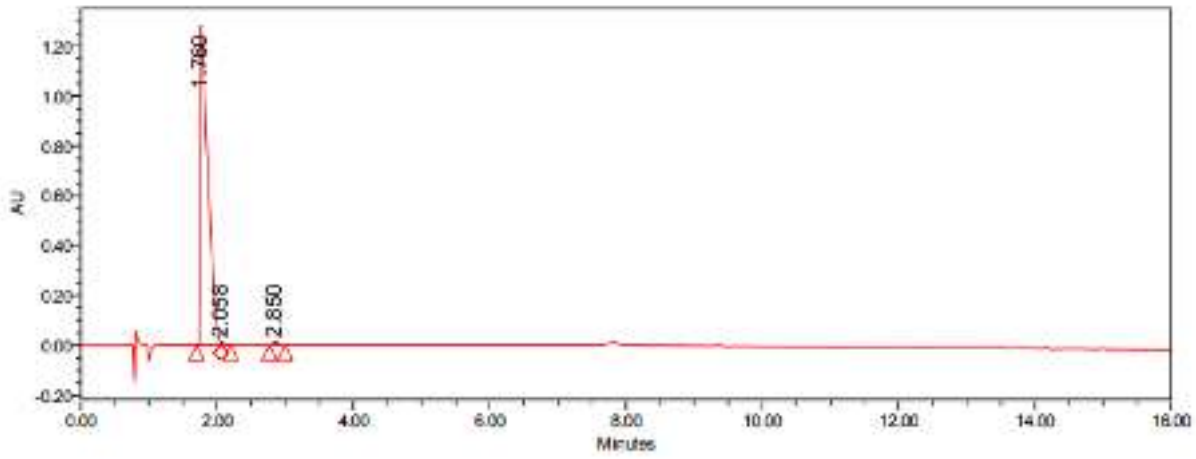
Channel Description ACQUITY TUV ChA 214nm

Vial : 1:A,3 Vol. : 2.50 ul

Date Acquired 11/7/2023 11:14:45 AM CET

Date Processed 11/23/2023 10:25:29 AM CET

Acq Method Set :
Gr_0_20_16min_40C_0_4_K1_met_s



	RT	Area	Height (µV)	% Area
1	1.760	10489022	1280249	98.93
2	2.058	36397	12335	0.34
3	2.850	76827	14832	0.72

A: 0.05% TFA in water
B: 0.05% TFA in acetonitrile
Gradient : 0-0/5min, 5-16min0--> 20% B, , 0.4ml/min
Acquity UPLC BEH130, 1.7um, 2.1 x 150 mm column
column own temp. = 40 °C

2.5 Result of purity assessment

The overall purity is 98.93 % at 214 nm.

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CONCLUSION:
The sample EPITHALON (Batch No. 2023179) was analyzed for peptide content and UV purity.

Peptide content is 108.3 % (5.42 mg in 5 mg)
Purity is 98.93 % (UPLC at 214 nm).

ANALYSIS COMPLETED:	Date: 07.11.2023
Issued by QC:	Date: 23.11.2023 Signature:

eurofins | BioPharma Product Testing

ilac-MRA SNAS Reg. No.031/S-106

Test Certificate No.:

23427-23429/2023

Testing laboratory	Customer
EUROFINS BELNOVAMANN s.r.o. Komjatická 73, 940 02 Nové Zámky IČO: 31 329 209 Place of work: **Testing laboratory Bratislava** Kollárovo nám. 9, 811 07 Bratislava tel.: 0911 810 533, fax: 02/52620178 CSPharmaSK@eurofins.sk, www.eurofins.sk	PARTICLE s.r.o. Kolonada 4490/18 984 01 Lučenec

Product information No.: 23427
Sample description: PT-141 (PO-2023177)
Gross weight (volume): 10 mg glass vials

Information about Sampling:
Sampler: customer

Sample reception date: 02.11.2023 **Date of Testing:** 02.11.2023 - 07.11.2023 **Certificate issued on:** 07.11.2023

Microbiological tests

Parameter	Unit	Allowed Value	Measured Value	Uncertainty*	Testing method	E	SL	TT
Bacterial endotoxins	IU / mg	m 1	<0,5	-	ŠPP MB.M.146.PN	S	PN	A

Product information No.: 23428
Sample description: Epithalon (PO-2023179)
Gross weight (volume): 5 mg glass vials

Information about Sampling:
Sampler: customer

Sample reception date: 02.11.2023 **Date of Testing:** 02.11.2023 - 07.11.2023 **Certificate issued on:** 07.11.2023

Microbiological tests

Parameter	Unit	Allowed Value	Measured Value	Uncertainty*	Testing method	E	SL	TT
Bacterial endotoxins	IU / mg	m 1	<0,5	-	ŠPP MB.M.146.PN	S	PN	A

Product information No.: 23429
Sample description: Melanotan 2 (PO-2023180)
Gross weight (volume): 10 mg glass vials

Information about Sampling:
Sampler: customer

Sample reception date: 02.11.2023 **Date of Testing:** 02.11.2023 - 07.11.2023 **Certificate issued on:** 07.11.2023

Microbiological tests

Parameter	Unit	Allowed Value	Measured Value	Uncertainty*	Testing method	E	SL	TT
Bacterial endotoxins	IU / mg	m 1	<0,5	-	ŠPP MB.M.146.PN	S	PN	A

EUROFINS BELNOVAMANN s.r.o. AKREDITOVANÉ SKÚŠOBNÉ LABORATÓRIUM SNAS č. S106

Notes:

E - evaluation
S - satisfied
NS - not satisfied
SPP, LS PP-01 - Standard operation procedure
ND - not detected by given method
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
* - Uncertainty determined by extension coefficient k=2 (with probability of 95%) does not include the uncertainty of sampling.
- Uncertainty given in units of analysed parameter reflects the uncertainty to the result of measurement.
- Uncertainty given in % reflects the uncertainty from the result of measurement.
SL - analysing laboratory: BA-Bratislava, PN-Piešťany

TT - type of test
(A) - accredited sampling
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:

The laboratory is not responsible for the information provided by the customer, which can affect the validity of the 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 Test Certificate and marked as non accredited test shall not be a subject of accreditation.
The result given in this Test Certificate and marked as sub - delivery is the result of a Subcontractor's pecuing made under the terms and conditions of a contract concluded with him.
It is not possible reproduce or incorporate the test certificate into promotional materials without laboratory written authorization!
SNAS is a Signatory to the Multilateral Agreement MRA LAC.

Test results have been electronically validated by: Ing. Terézia Lopatová

Worked out by: Bc. Martin Tóth
Document No.: 1256/2023

Test Certificate approved by:
Ing. Terézia Lopatová
Specialist