

Pen peptide certificate of analysis (CoA)

Product:	Epitalon		
Source:	Hybrid synthesis (recombinant using peptide secretion system and chemical synthesis)		
Intended use:	For stability, viability and activity testing only.		
Order number:		Lot:	25AUG03EPI
Production:	08/2025	Expiry:	08/2027
Formulation:	0.2 µm-filtered solution in 20mM glycine, 200mM Mannitol, 20mM NaH ₂ PO ₄ , pH 7.4; m-cresol 1 mg/ml, glycerol 2 mg/ml (when liquid)		
Protein/peptide concentration per 3 ml cartridge:	30 mg		

<u>Release Testing:</u>	<u>Specification</u>	<u>Lot Result</u>
Purity:	≥ 97%	> 98%
Identity:	Complies	Complies
Sterility:	Sterile	Complies
Endotoxin level:	< 10 EU/mg	< 0.20 EU/mg
Host-cell DNA	≤ 200 ng/mg	Complies (1.1 ng/mg)

Activity was determined using in vitro test.

Purity was determined by HPLC.

Identity was confirmed by end-of-production DNA sequencing and N-terminal protein sequencing.

Sterility test of vial product was performed according to Eur.Pharm. (Inoculation method).

Endotoxin was determined using the gel clot assay according to Eur.Pharm.

Host-cell DNA/RNA was determined using fluorimetric assay (if applicable).

Handling Instructions:

General usage: Open cap, clean the rubber stopper with disinfectant napkin or other cleaning disinfection method / material. Puncture rubber stopper with sterile needle by screwing needle on. Remove the plastic protective cover. Set the index to physician prescribed position, remove the pink plastic cover and let out the air from the cartridge by several button presses into the air. Put on the plastic protective cover back.

Using liquid product: Liquid products are ready to use according to physician recommendations.

Storage and stability: Store material at +2 - +8°C. **Do not freeze!**

Quality Statement:

This product is manufactured, tested and realized in compliance with the relevant GMP-guidelines. No animal- or human-derived materials were used during manufacturing. USP chapter <1043> “ancillary materials for cell, gene, and tissue-engineered product” has been considered in the design of this product.

Stability report

Epitalon

Data Provided:

- Initial concentration of Epitalon: **97,87%**.
- Concentration after 7 days at:
 - **+4°C: 98.38%**.
 - **+42°C: 96.06%**.

Analysis Plan:

- Use the Arrhenius equation to calculate the degradation rate constants.
- Determine the activation energy (Ea) based on the temperature and degradation rates.
- Predict time to 90% stability at **+4°C**.

Summary of Results:

- **Activation Energy (Ea): 50 kJ/mol.**
- **Time to 90% Stability at +4°C: 303 days.**

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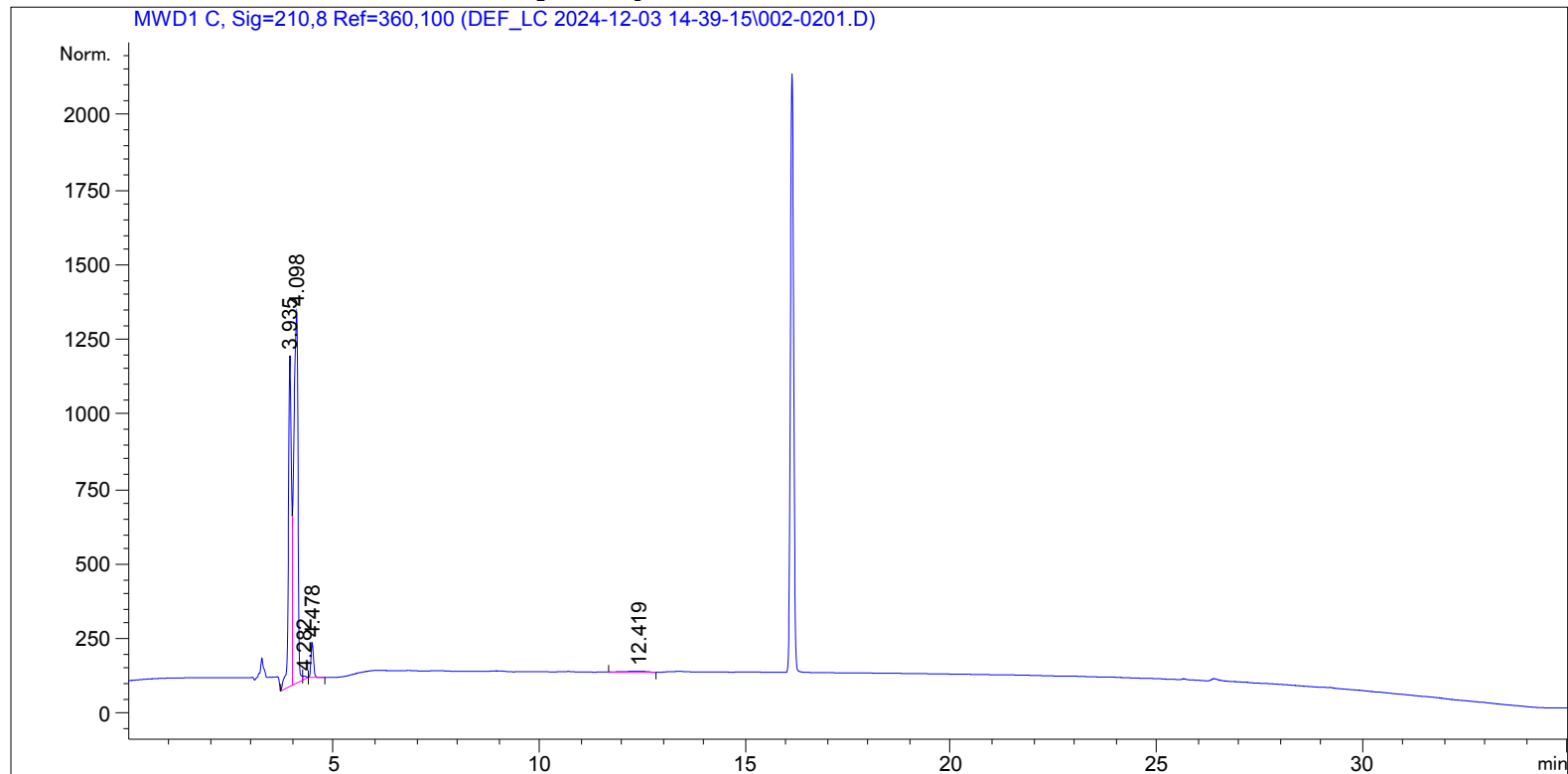
Acq. Operator	:		Seq. Line	:	2
Acq. Instrument	:	Instrument 1	Location	:	Vial 2
Injection Date	:	12/3/2024 3:22:38 PM	Inj	:	1
			Inj Volume	:	10.0 µl

Different Inj Volume from Sequence ! Actual Inj Volume : 5.0 µl

Acq. Method	:	C:\CHEM32\1\DATA\DEF_LC 2024-12-03 14-39-15\C18 RP-HPLC ACN 5-95 30 MIN.M
Last changed	:	7/31/2024 10:51:05 AM
Analysis Method	:	C:\CHEM32\1\METHODS\C414\C4 GLP1 30-70 ACN.M
Last changed	:	12/19/2024 1:44:58 PM

(modified after loading)

Additional Info : Peak(s) manually integrated



Area Percent Report

Sorted By : Signal
Multiplier : 1.0000
Dilution : 1.0000
Use Multiplier & Dilution Factor with ISTDs

Signal 1: MWD1 C, Sig=210,8 Ref=360,100

Peak #	RetTime [min]	Type	Width [min]	Area [mAU*s]	Height [mAU]	Area %
1	3.935	BV	0.0782	5711.90723	1106.84985	37.6531
2	4.098	VV	0.1144	8770.69629	1241.12964	57.8167
3	4.282	VB	0.0774	60.05171	11.05918	0.3959
4	4.478	BB	0.0650	489.75021	116.50581	3.2284
5	12.419	VB	0.5102	137.42598	3.33851	0.9059

Totals : 1.51698e4 2478.88300

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*** End of Report ***

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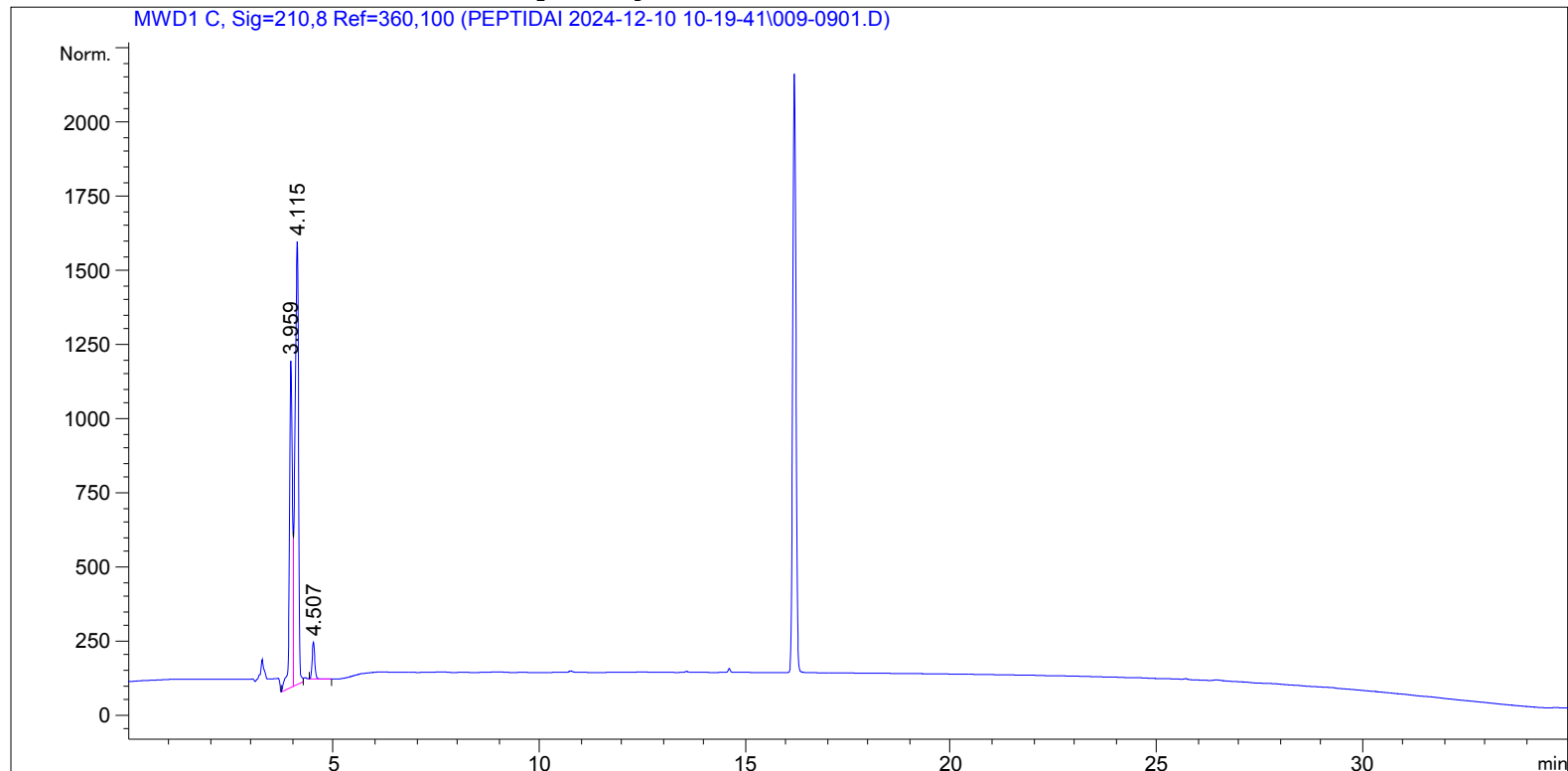
Acq. Operator	:		Seq. Line	:	9
Acq. Instrument	:	Instrument 1	Location	:	Vial 9
Injection Date	:	12/10/2024 3:52:17 PM	Inj	:	1
			Inj Volume	:	10.0 µl

Different Inj Volume from Sequence ! Actual Inj Volume : 5.0 µl

Acq. Method	:	C:\CHEM32\1\DATA\PEPTIDAI 2024-12-10 10-19-41\C18 RP-HPLC ACN 5-95 30 MIN.M
Last changed	:	7/31/2024 10:51:05 AM
Analysis Method	:	C:\CHEM32\1\METHODS\C414\C4 GLP1 30-70 ACN.M
Last changed	:	12/19/2024 1:44:58 PM

(modified after loading)

Additional Info : Peak(s) manually integrated



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Area Percent Report

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Sorted By : Signal
Multiplier : 1.0000
Dilution : 1.0000
Use Multiplier & Dilution Factor with ISTDs

Signal 1: MWD1 C, Sig=210,8 Ref=360,100

Peak #	RetTime [min]	Type	Width [min]	Area [mAU*s]	Height [mAU]	Area %
1	3.959	BV	0.0753	5616.87891	1105.37915	37.4710
2	4.115	VV	0.0929	8830.02344	1495.62036	58.9063
3	4.507	BB	0.0669	543.05231	124.48878	3.6228

Totals : 1.49900e4 2725.48829

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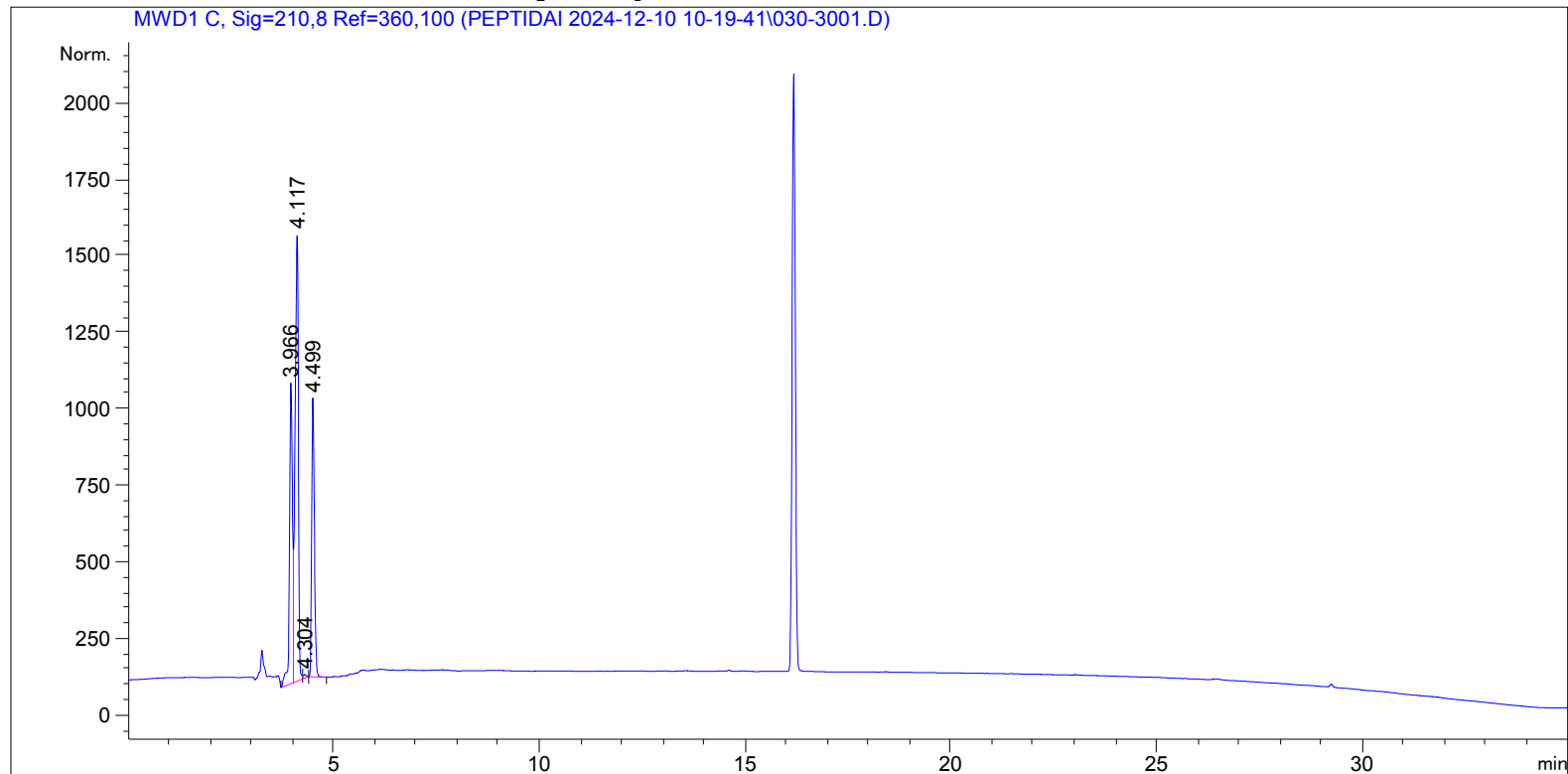
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Acq. Operator	:		Seq. Line	:	30
Acq. Instrument	:	Instrument 1	Location	:	Vial 30
Injection Date	:	12/11/2024 6:25:02 AM	Inj	:	1
			Inj Volume	:	10.0 µl

Different Inj Volume from Sequence ! Actual Inj Volume : 5.0 µl

Acq. Method : C:\CHEM32\1\DATA\PEPTIDAI 2024-12-10 10-19-41\C18 RP-HPLC ACN 5-95 30 MIN.M
Last changed : 7/31/2024 10:51:05 AM
Analysis Method : C:\CHEM32\1\METHODS\C414\C4 GLP1 30-70 ACN.M
Last changed : 12/19/2024 3:11:46 PM
(modified after loading)

Additional Info : Peak(s) manually integrated



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Area Percent Report

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Sorted By : Signal
Multiplier : 1.0000
Dilution : 1.0000
Use Multiplier & Dilution Factor with ISTDs

Signal 1: MWD1 C, Sig=210,8 Ref=360,100

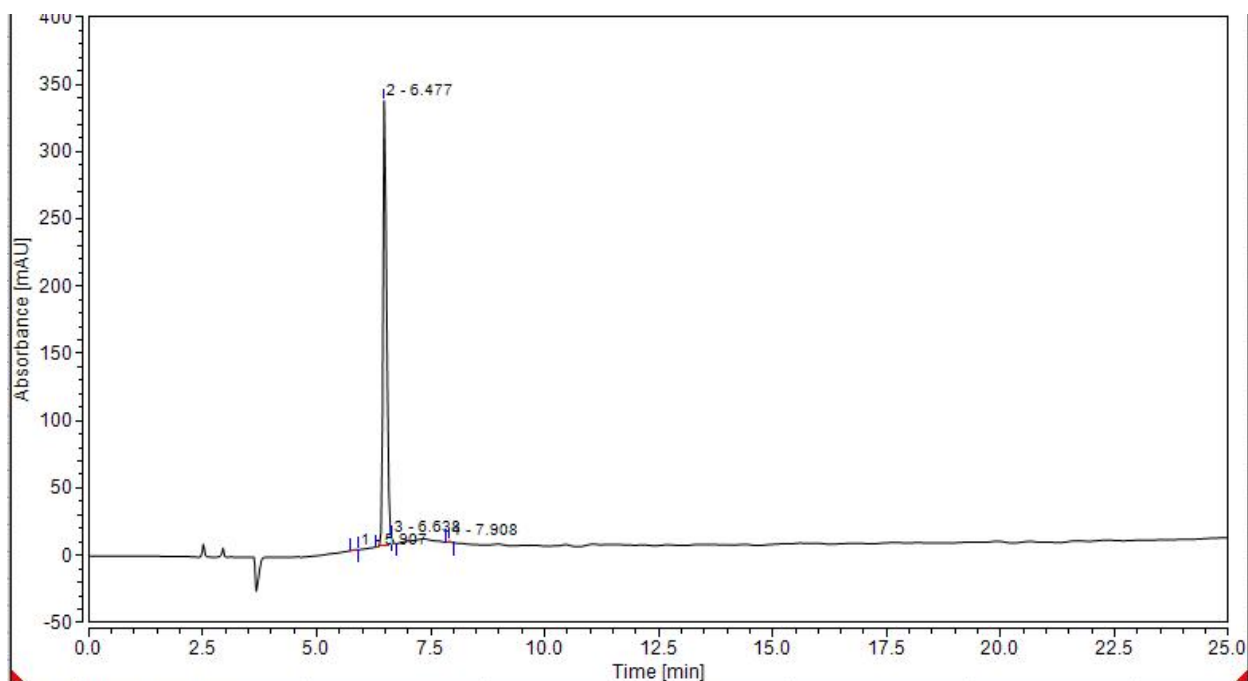
Peak #	RetTime [min]	Type	Width [min]	Area [mAU*s]	Height [mAU]	Area %
1	3.966	BV	0.0752	4979.30762	981.99884	28.6485
2	4.117	VV	0.0893	8175.76855	1460.46021	47.0393
3	4.304	VB	0.0772	64.95638	11.99884	0.3737
4	4.499	BB	0.0713	4160.67578	911.16937	23.9385

Totals : 1.73807e4 3365.62726

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*** End of Report ***

Sample Information

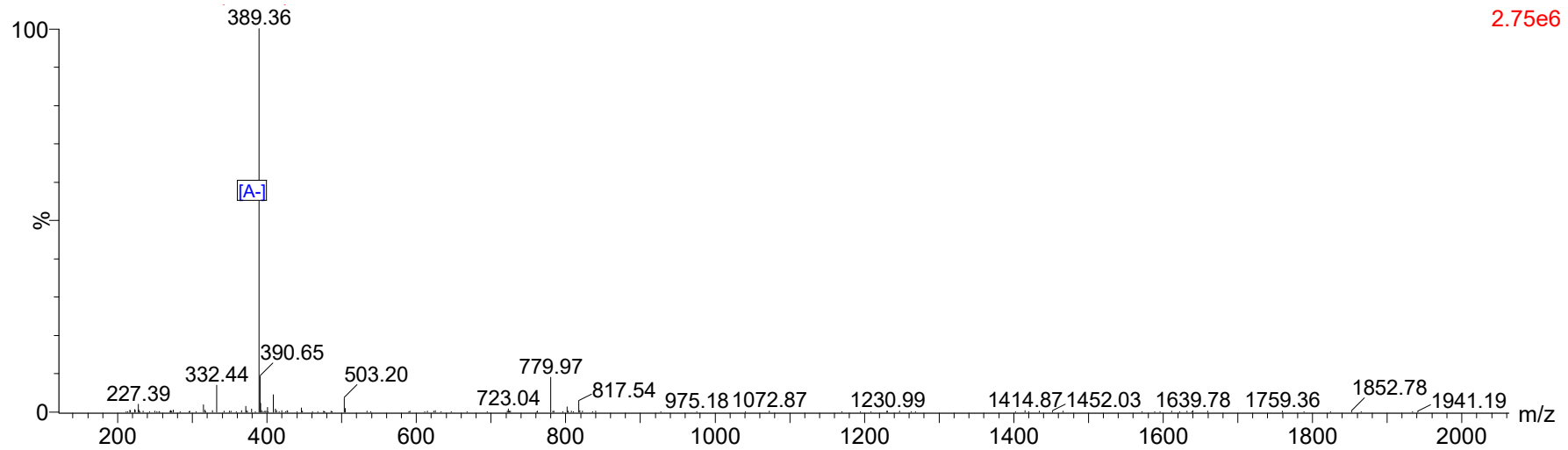
Product Name :Epithalon
 Lot. No :20250803
 Sequence :Ala-Glu-Asp-Gly
 Column : Welch,XB-C18,(4.6mm i.d.,250 mm L)
 Buffer : A: 0.1% TFA in Acetonitrile B: 0.1% TFA in H2O
 Gradient :1-26% in 25 min
 Flow rate :1.0ml/min
 Wavelength :220nm
 Dissolution method :100%H2O



Integration Results							
No.	Peak Name	Retention Time	Area	Height	Relative Area	Relative Height	Amount
		min	mAU*min	mAU	%	%	n.a.
1		5.907	0.028	0.000	0.09	0.00	n.a.
2		6.477	30.442	330.642	99.13	98.28	n.a.
3		6.638	0.163	4.716	0.53	1.40	n.a.
4		7.908	0.076	1.072	0.25	0.32	n.a.
Total:			30.708	336.430	100.00	100.00	

MS Spectrum

2.75e6



Dissolution	:0.1%HCOOH+ACN	Interface	:ESI	Prerod Bias	:+3.5kv
Date	:2025/08/03 9:29:40	Nebulizing Gas Flow	:500L/hr	Detector	:-0.2kv
Injection	:2.5ul	CDL Temp	:400C	T.Flow	:0.35ml/min
Block Temp	:150	CDL Volt	:-10v	B.conc	:50%H2O/50%MEOH

Product Name : Epithalon
 Sequence : Ala-Glu-Asp-
 Lot.No Gly : 20250803
 Theoretical : 390.35
 Observed : 390.36