

Pen peptide certificate of analysis (CoA)

Product:	TB500
Source:	Hybrid synthesis (recombinant using peptide secretion system and chemical synthesis)
Intended use:	For stability, viability and activity testing only.
Order number:	Lot: 25AUG13TB5
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:	15 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 a Nb2-11 cell proliferation assay.

Purity was determined by SDS PAGE and coomassie stain (under reducing and non-reducing conditions).

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 was determined using fluorimetric assay.

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

TB500

Data Provided:

- Initial concentration of TB500: **100%**.
- Concentration after 7 days at:
 - **+4°C: 99,35%**.
 - **+42°C: 101,77%**.

Analysis Plan:

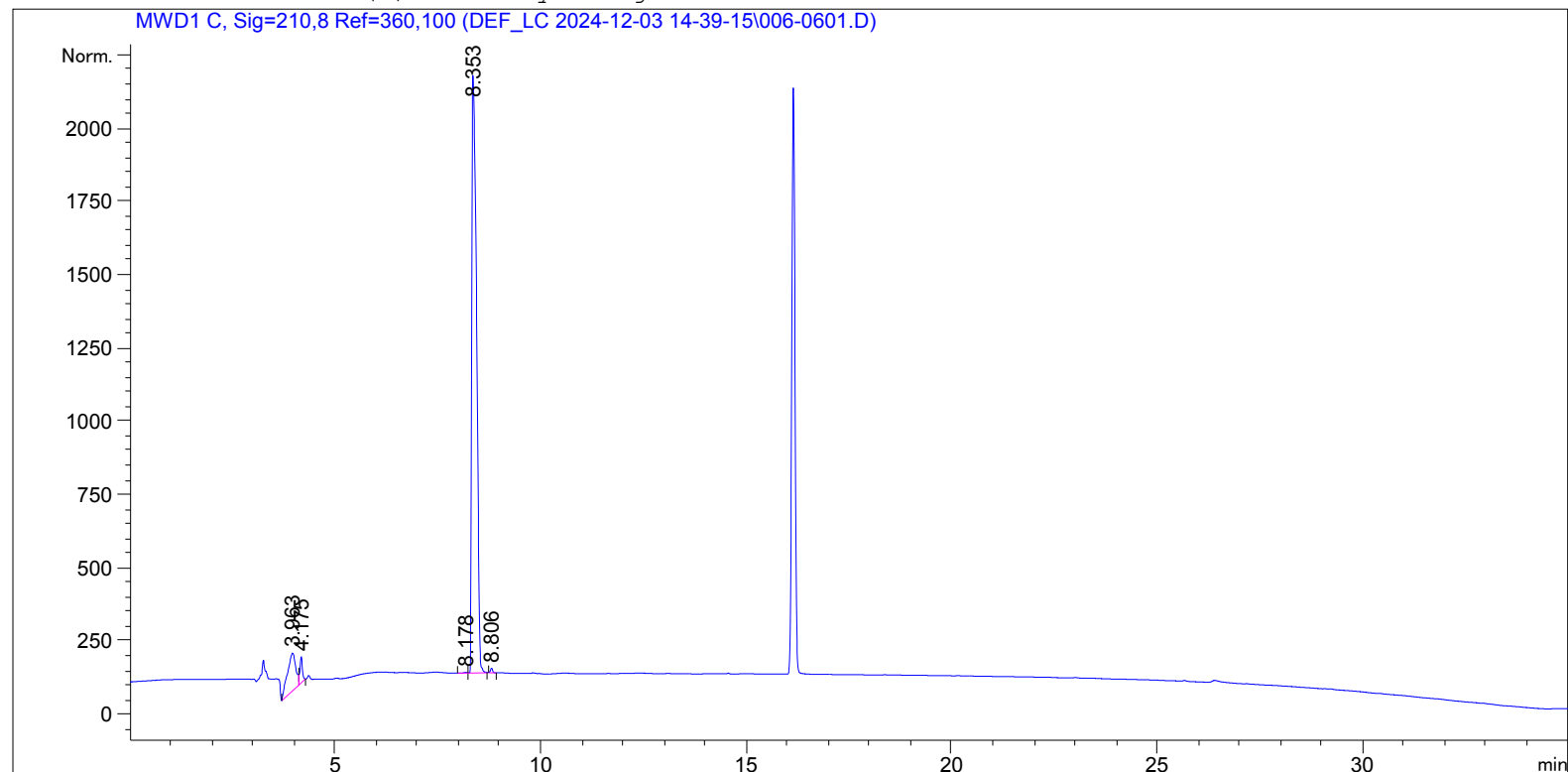
- Use the Arrhenius equation to calculate the degradation rate constants.
- Determine the activation energy (E_a) based on the temperature and degradation rates.
- Predict time to 90% stability at **+4°C**.

Summary of Results:

- **Activation Energy (E_a): 10 kJ/mol.**
- **Time to 90% Stability at +4°C: not possible to calculate, need more distant point as this is stable at 7 days at 42°C.**

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Acq. Operator	:		Seq. Line	:	6
Acq. Instrument	:	Instrument 1	Location	:	Vial 6
Injection Date	:	12/3/2024 6:08:47 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					



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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	3.963	BV	0.2075	1816.19080	128.03923	9.6292
2	4.175	VB	0.0648	389.05090	89.40221	2.0627
3	8.178	BV	0.0736	12.90102	2.52670	0.0684
4	8.353	VV	0.1387	1.65827e4	2043.52014	87.9191
5	8.806	VB	0.0610	60.46994	15.66416	0.3206

Totals : 1.88613e4 2279.15244

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*** End of Report ***

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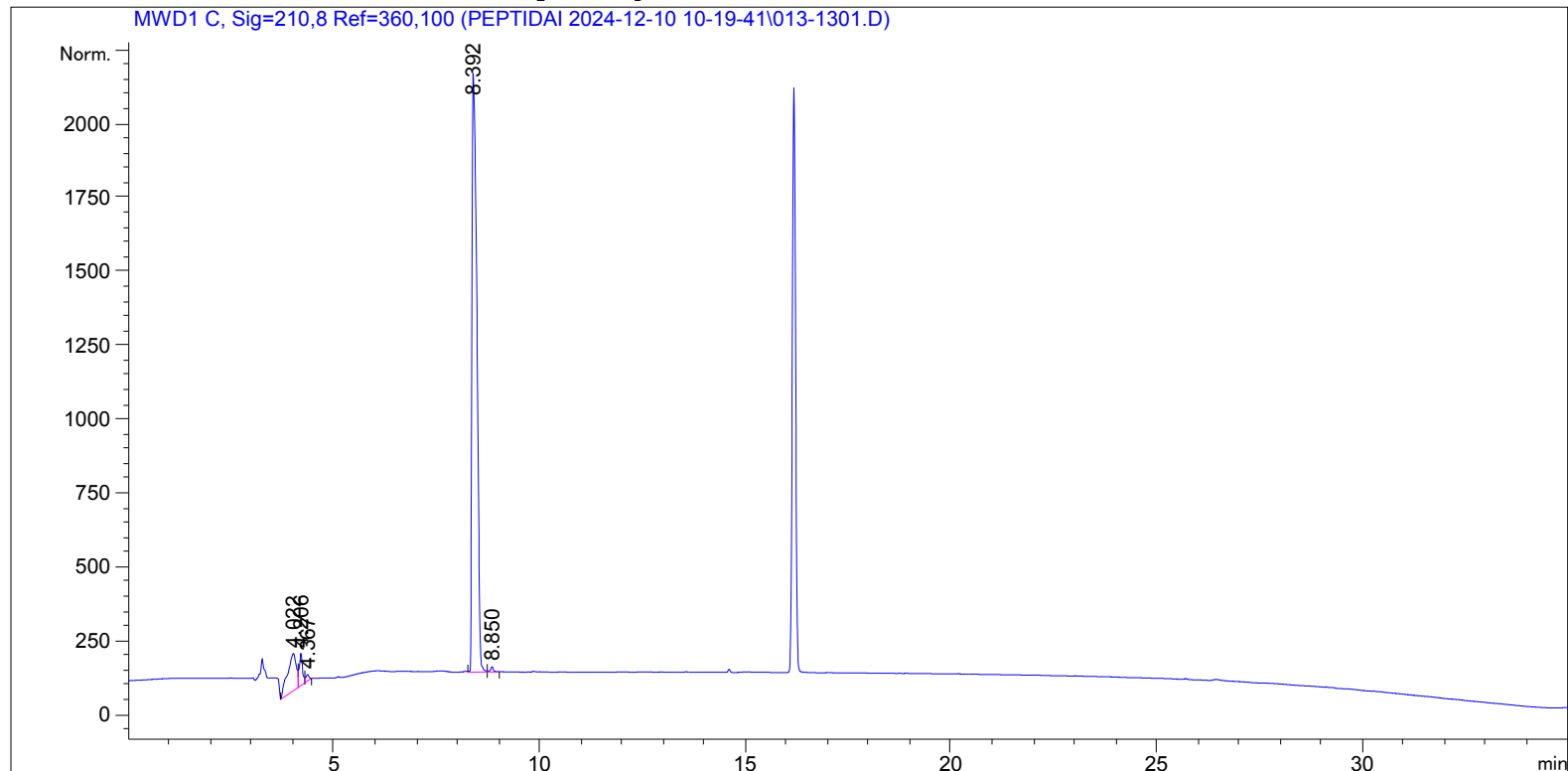
Acq. Operator	:		Seq. Line	:	13
Acq. Instrument	:	Instrument 1	Location	:	Vial 13
Injection Date	:	12/10/2024 6:38:40 PM	Inj	:	1
			Inj Volume	:	10.0 µl

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 3:04:50 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

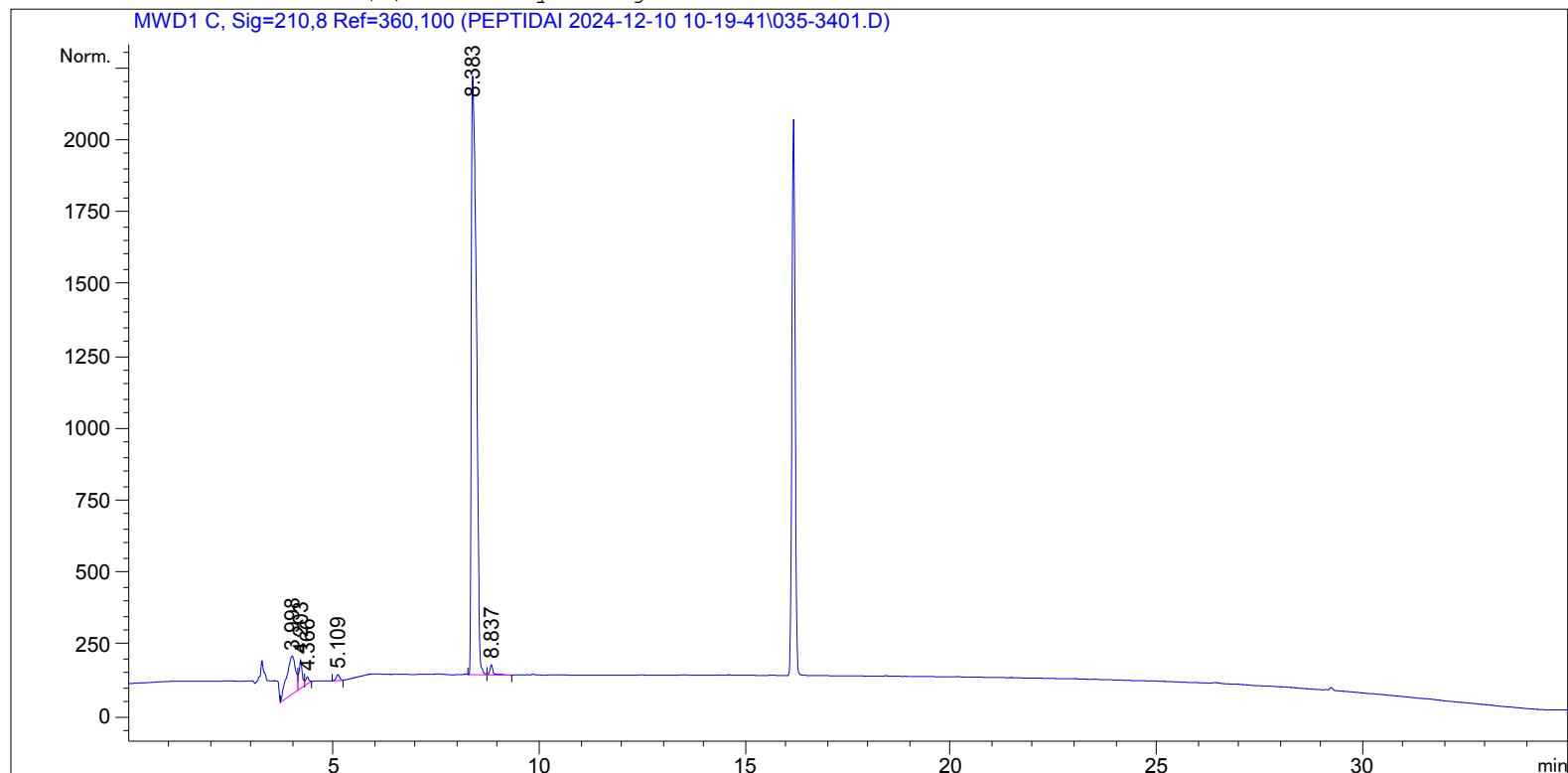
Peak #	RetTime [min]	Type	Width [min]	Area [mAU*s]	Height [mAU]	Area %
1	4.022	BV	0.2157	1889.75757	125.48964	9.6887
2	4.206	VV	0.0783	604.04437	109.51669	3.0969
3	4.367	VB	0.0823	126.41939	22.24979	0.6481
4	8.392	VV	0.1405	1.67924e4	2030.24744	86.0934
5	8.850	VV	0.0777	92.24317	17.45463	0.4729

Totals : 1.95048e4 2304.95817

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*** End of Report ***

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Acq. Operator	:		Seq. Line	:	34
Acq. Instrument	:	Instrument 1	Location	:	Vial 35
Injection Date	:	12/11/2024 9:11:17 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 4:40:41 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	3.998	BV	0.2211	1998.10010	131.60873	9.7061
2	4.203	VV	0.0806	546.05591	98.60164	2.6526
3	4.366	VB	0.0801	136.06322	24.02088	0.6609
4	5.109	BB	0.0870	110.54110	19.83467	0.5370
5	8.383	BV	0.1467	1.76041e4	2079.81348	85.5148
6	8.837	VB	0.0788	191.18173	35.49316	0.9287

Totals : 2.05861e4 2389.37256

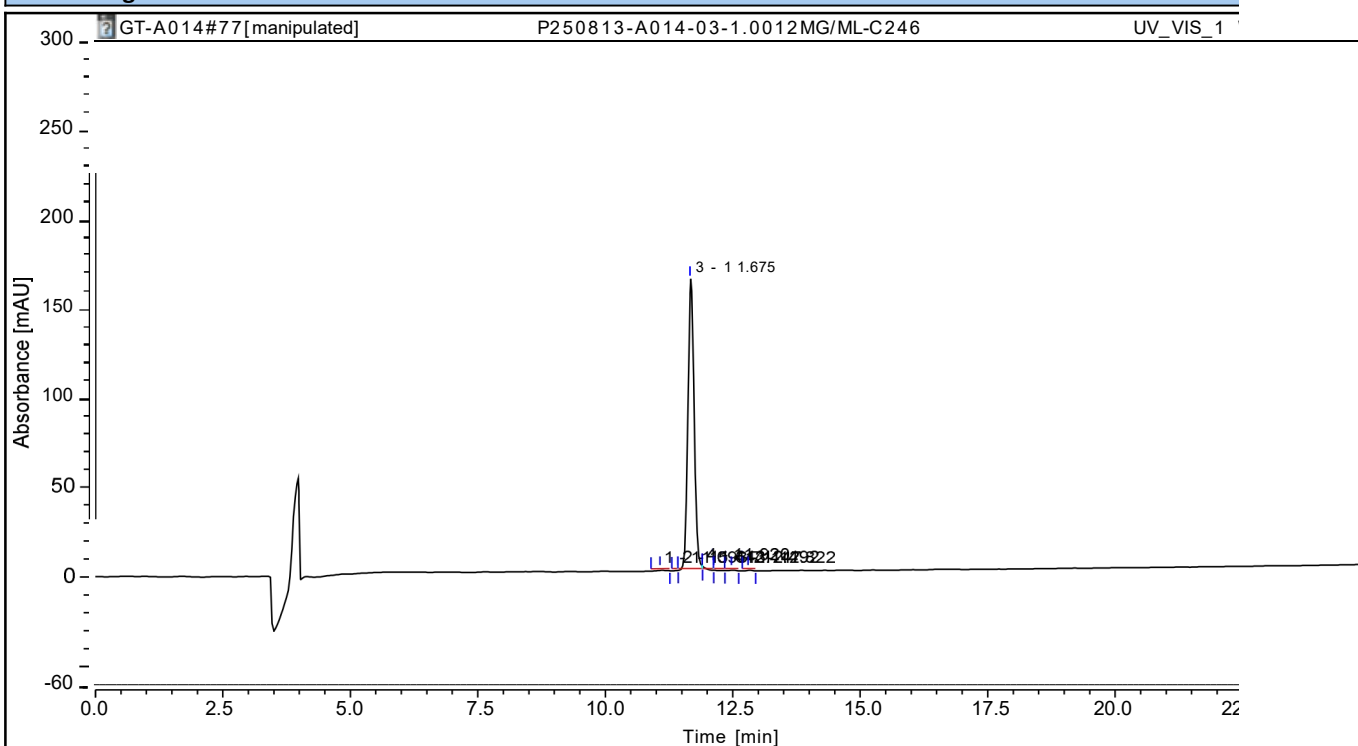
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*** End of Report ***

Chromatogram and Results

Injection Details

Injection Name:	20250813-TB500	Run Time (min):	41.00
Vial Number:	GC3	Injection Volume:	10.00
Injection Type:	Unknown	Channel:	UV_VIS_1
Calibration Level:		Wavelength:	229.0
Instrument Method:	TFA	Bandwidth:	n.a.
Processing Method:	New ProcMethod-N	Dilution Factor:	1.0000
Injection Date/Time:	2025-08-13 10:15:14	Sample Weight:	1.0000

Chromatogram

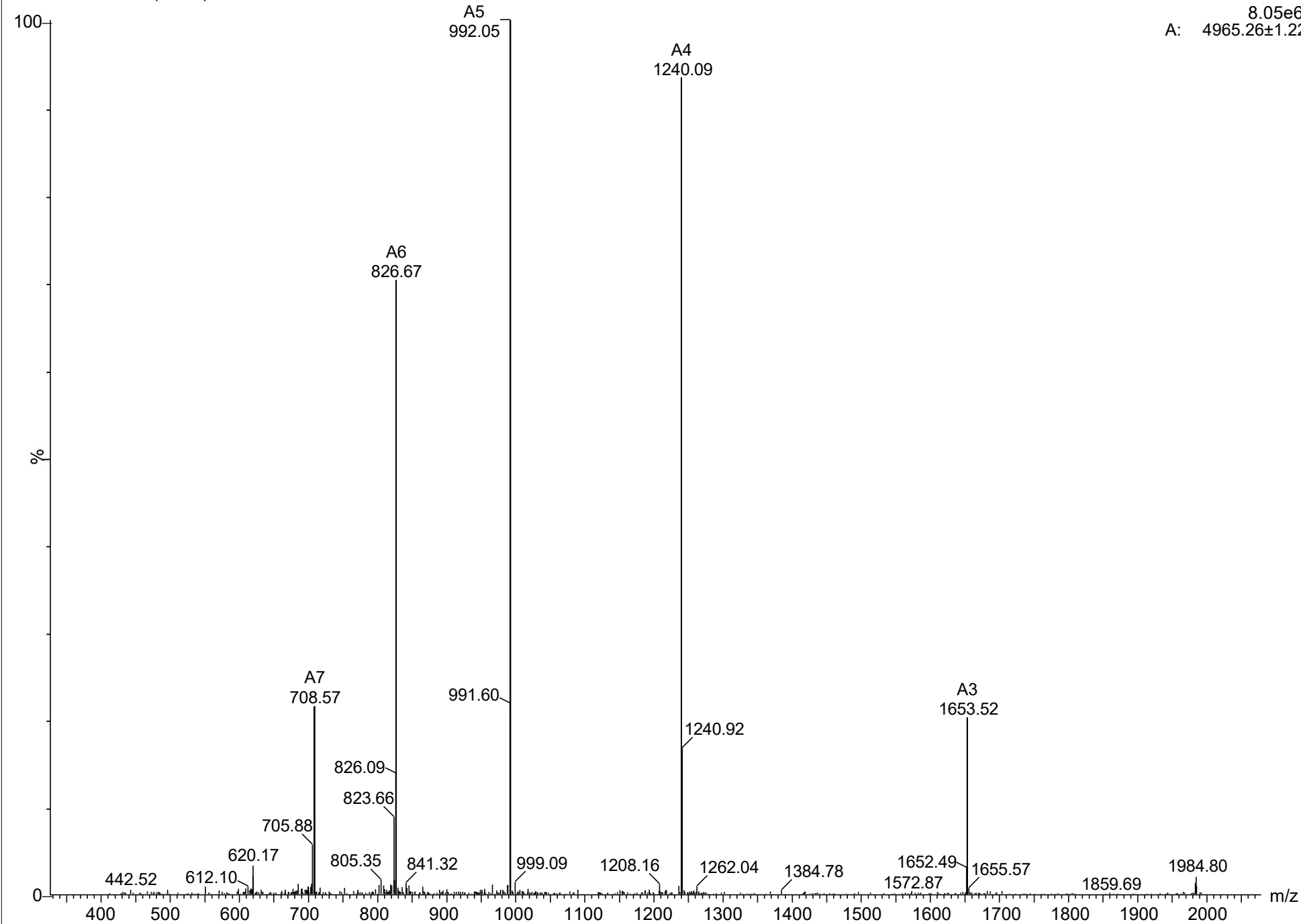


Integration Results

No.	Peak Name	Retention Time min	Area mAU*min	Height mAU	Relative Area %	Relative Height %
1		11.093	0.063	0.329	0.27	0.20
2		11.443	0.015	0.344	0.06	0.21
3		11.675	23.140	163.432	98.33	97.82
4		11.920	0.185	2.051	0.79	1.23
5		12.147	0.039	0.237	0.17	0.14
6		12.492	0.051	0.329	0.22	0.20
7		12.822	0.042	0.347	0.18	0.21
Total:			23.534	167.068	100.00	100.00

20250813-TB500 (0.272)

Scan ES-
8.05e6
A: 4965.26±1.22



TEST REPORT



E-mail: info@janoshik.com
Web: www.janoshik.com

Task Number #49666

Testing ordered > 20 SEP '24

Sample received > 25 SEP '24

Client Pen Peptide

Sample TB-500

Manufacturer Unknown

Batch Unknown

Sample description >

Pictures not included.

Tests requested >

Assessment of a peptide vial or vials.

Results >



TB-500 (TB-4)	8.88 mg
Purity	99.017%

Comments >

Analysis conducted > 30 SEP 2024

Signature >

Verify this test at www.janoshik.com/verify/ with the following unique key

9LAAHIEPTBH1