Pen peptide certificate of analysis (CoA)

Product:	**BPC-157**		
Source:	Hybrid synthesis (recombinant using peptide secretion system and chemical synthesis)		
Intended use:	For stability, viability and activity testing only.		
Order number:		**Lot:**	25AUG18BPC
Production:	08/2025	**Expiry:**	08/2027
Formulation:	0.2 µm-filtered solution in 20mM glycine, 200mM Mannitol, 20mM NaH_2PO_4, pH 5.2; m-cresol 1 mg/ml, glycerol 2 mg/ml (when liquid)		
Protein/peptide concentration per 3 ml cartridge:	15 mg		

Release Testing:	**Specification**	**Lot Result**
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 vialed 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^{0}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.

GETPEPTIDES.AE

Stability report

BPC157

Data Provided:

- Initial concentration of BPC157: **97,87%**.
- Concentration after 7 days at:
  - **+4°C**: **98.38%**.
  - **+42°C**: **97.74%**.

Analysis Plan:

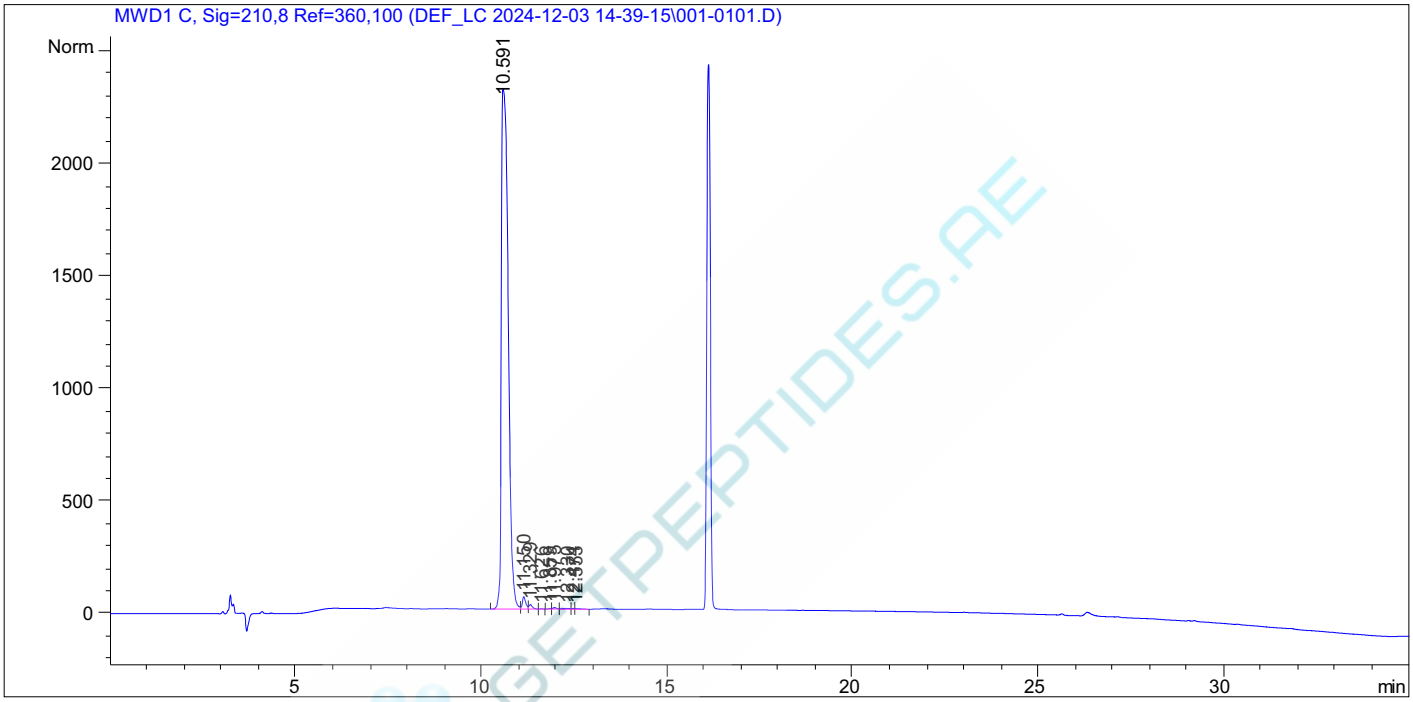
- Use the Arrhenius equation to calculate the degradation rate constants.
- Determine the activation energy (Ea) based on the temperature and degradation rates.
- Predict time to 90% stability at **+4°C**.

Summary of Results:

- **Activation Energy (Ea)**: **10 kJ/mol**.
- **Time to 90% Stability at +4°C**: **745 days**.

Data File C:\CHEM32\1\DATA\DEF_LC 2024-12-03 14-39-15\001-0101.D
Sample Name: BPC157 5mg/ml 24-12-03

```
==========================================================================
Acq. Operator   :                                   Seq. Line :   1
Acq. Instrument : Instrument 1                       Location : Vial 1
Injection Date  : 12/3/2024 2:40:46 PM                    Inj :   1
                                                  Inj Volume : 10.0 µl
Differen t 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	10.591	BV	0.2062	2.97343e4	2310.18726	97.8790
2	11.150	VV	0.0937	349.01669	55.22498	1.1489
3	11.329	VB	0.0933	124.27836	19.79065	0.4091
4	11.626	BB	0.0632	7.76154	1.84178	0.0255
5	11.859	BV	0.0769	13.04873	2.58322	0.0430
6	11.975	VV	0.1051	51.53316	7.06810	0.1696
7	12.330	VV	0.2207	48.89796	2.78742	0.1610
8	12.474	VV	0.0875	17.46401	2.77280	0.0575

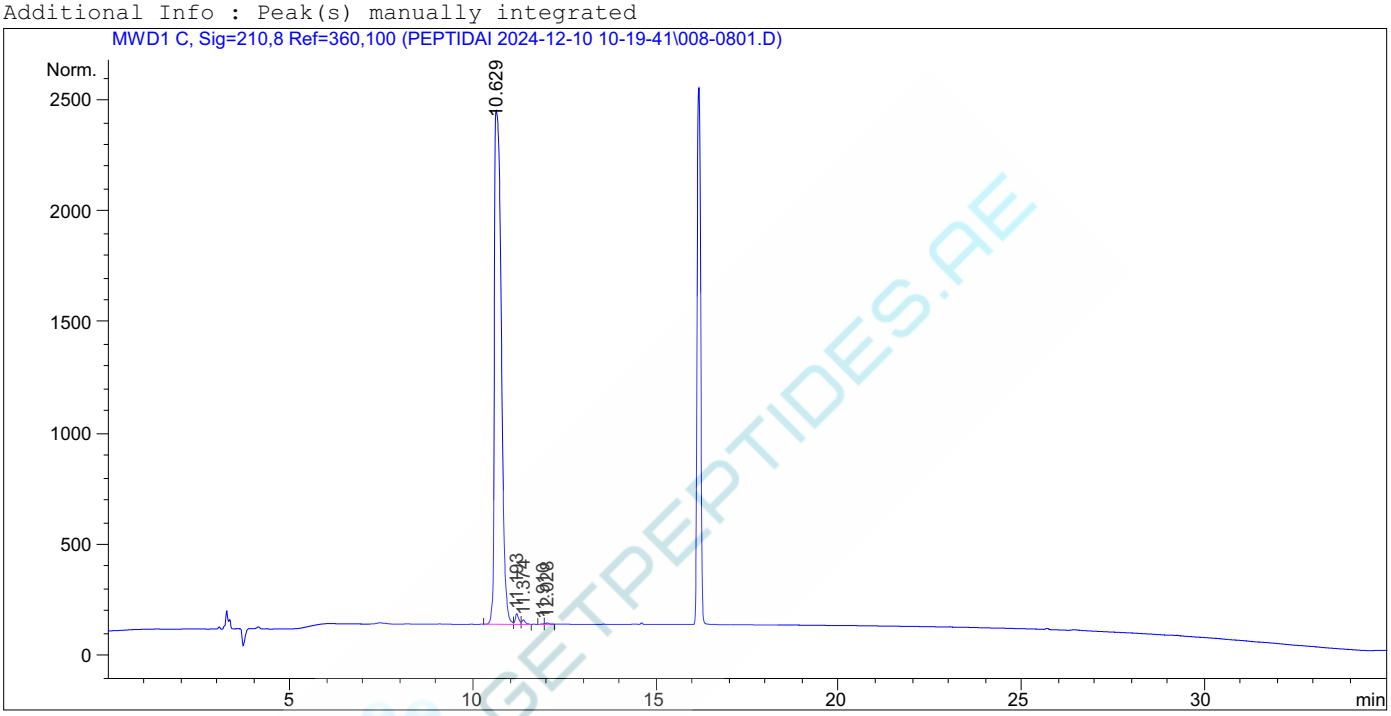
Data File C:\CHEM32\1\DATA\DEF_LC 2024-12-03 14-39-15\001-0101.D
Sample Name: BPC157 5mg/ml 24-12-03

Peak #	RetTime [min]	Type	Width [min]	Area [mAU*s]	Height [mAU]	Area %
9	12.553	VB	0.1548	32.32976	2.79820	0.1064
Totals :				3.03787e4	2405.05440	

*** End of Report ***

Data File C:\CHEM32\1\DATA\PEPTIDAI 2024-12-10 10-19-41\008-0801.D
Sample Name: BPC157 5mg/ml 4C 24-12-10

```
=====================================================================
Acq. Operator   :                                Seq. Line :   8
Acq. Instrument : Instrument 1                    Location : Vial 8
Injection Date  : 12/10/2024 3:10:43 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
=====================================================================

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 Type  Width     Area      Height     Area
  #   [min]        [min]   [mAU*s]     [mAU]       %
----|-------|----|-------|----------|----------|--------|
   1  10.629 BV    0.2098 3.00958e4  2313.23926  98.3879
   2  11.193 VV    0.0959  310.81635   47.79201   1.0161
   3  11.374 VB    0.0938  130.38831   20.05757   0.4263
   4  11.910 BV    0.0814   12.79684    2.43316   0.0418
   5  12.028 VB    0.0936   39.11422    6.20408   0.1279

Totals :                  3.05890e4  2389.72607
```

Data File C:\CHEM32\1\DATA\PEPTIDAI 2024-12-10 10-19-41\008-0801.D
Sample Name: BPC157 5mg/ml 4C 24-12-10

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*** End of Report ***

Data File C:\CHEM32\1\DATA\PEPTIDAI 2024-12-10 10-19-41\029-2901.D
Sample Name: BPC157 5mg/ml 42C 24-12-10

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    ======================================================================
    Acq. Operator   :                                  Seq. Line :  29
    Acq. Instrument : Instrument 1                      Location : Vial 29
    Injection Date  : 12/11/2024 5:43:27 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
```

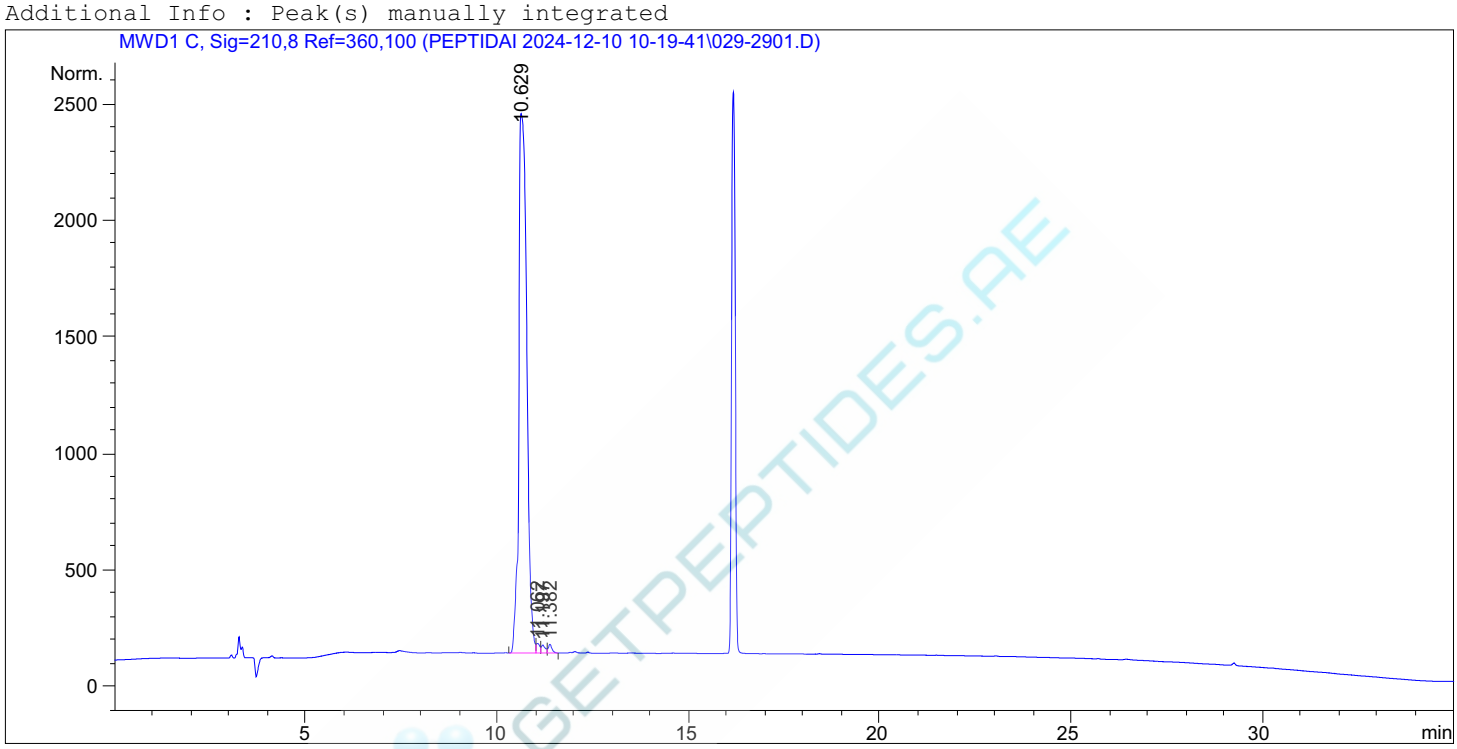


```
    ======================================================================
                              Area Percent Report
    ======================================================================

    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 Type  Width     Area      Height     Area
      #   [min]        [min]   [mAU*s]     [mAU]       %
    ----|-------|----|-------|----------|----------|--------|
       1  10.629 BV    0.2279 3.33230e4  2315.16260  97.7427
       2  11.062 VV    0.0987  270.72726   41.20023   0.7941
       3  11.197 VV    0.1024  250.92725   33.86735   0.7360
       4  11.382 VB    0.0972  247.91443   37.46213   0.7272

    Totals :                  3.40926e4  2427.69231
```

Data File C:\CHEM32\1\DATA\PEPTIDAI 2024-12-10 10-19-41\029-2901.D
Sample Name: BPC157 5mg/ml 42C 24-12-10

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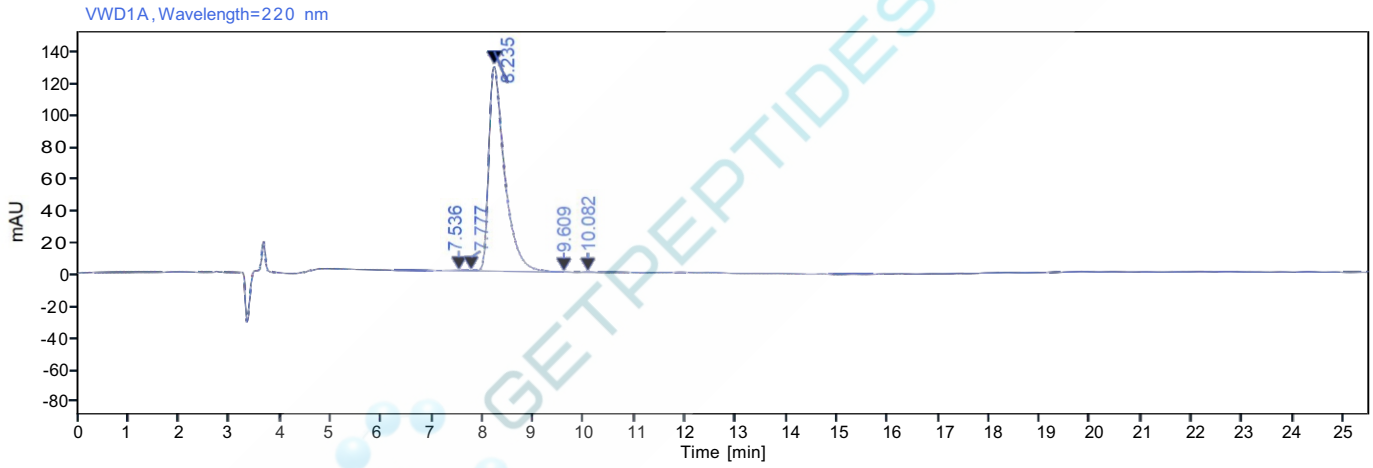
*** End of Report ***

Single Injection Report

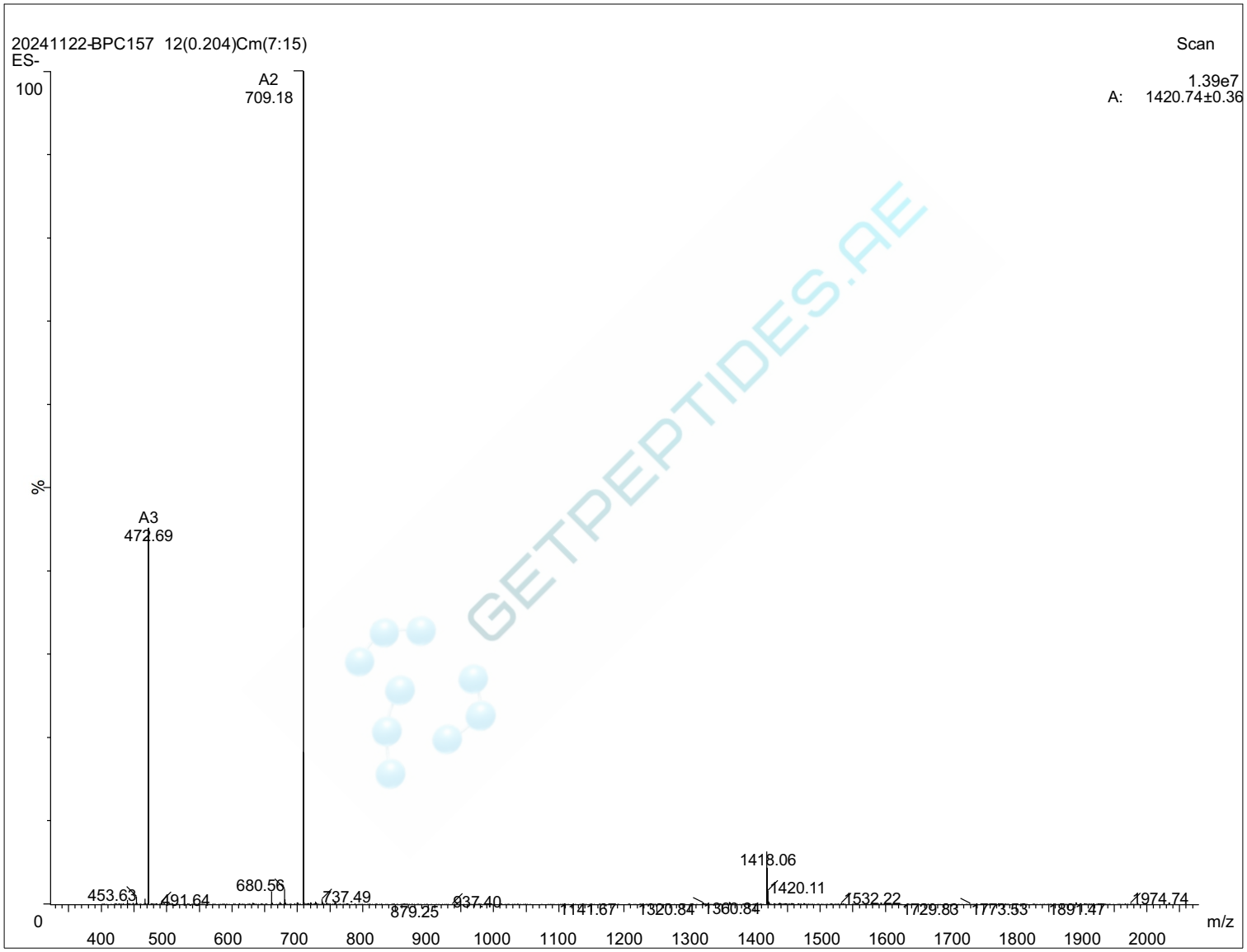
Agilent

Data file:	2025-08-18 23-13-54+08-00-03-r002.dx		
Sequence Name:	Agilent-1-2024-12-11 17-39-17+08-00	**Project Name:**	BPC157
Sample name:	20250818BPC157 .014MG/ML-C242	**Operator:**	SYSTEM (SYSTEM)
Instrument:	Agilent-1	**Injection date:**	2025-08-18 21:11:39+08:00
Inj. volume:	5.000 µL	**Location:**	P1-B3
Acq. method:	A015-TFA.amx	**Type:**	Sample
Processing method:	*TFA.pmx	**Sample amount:**	0.00
Manually modified:	Manual Integration		



Signal: VWD1A,Wavelength=220 nm

RT [min]	*Type*	*Width [min]*	*Area*	*Height*	*Area%*	*Name*	*Peak Theoretical Plates USP*
7.536	MM m	0.37	2.42	0.25	0.09		
7.777	MM m	0.35	7.92	0.46	0.28		
8.235	MM m	1.57	2782.47	127.58	99.44		
9.609	MB m	0.38	1.96	0.12	0.07		
10.082	MM m	0.55	3.28	0.21	0.12		
		Sum	2798.06				


20241122-BPC157 12(0.204)Cm(7:15)
ES-
Scan
100
A2
709.18
1.39e7
A: 1420.74±0.36
%
A3
472.69
1418.06
1420.11
453.63
491.64
680.56
737.49
879.25
937.40
1141.67
1320.84
1360.84
1532.22
1729.80
1773.53
1891.47
1974.74
0
m/z
400
500
600
700
800
900
1000
1100
1200
1300
1400
1500
1600
1700
1800
1900
2000