

## 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<sub>2</sub>PO<sub>4</sub>, pH 5.2; 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>    |
|-------------------------|----------------------|----------------------|
| <b>Purity:</b>          | ≥ 97%                | > 98%                |
| <b>Identity:</b>        | Complies             | Complies             |
| <b>Sterility:</b>       | Sterile              | Complies             |
| <b>Endotoxin level:</b> | < 10 EU/mg           | < 0.20 EU/mg         |
| <b>Host-cell DNA</b>    | ≤ 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

### BPC157

#### Data Provided:

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

#### Analysis Plan:

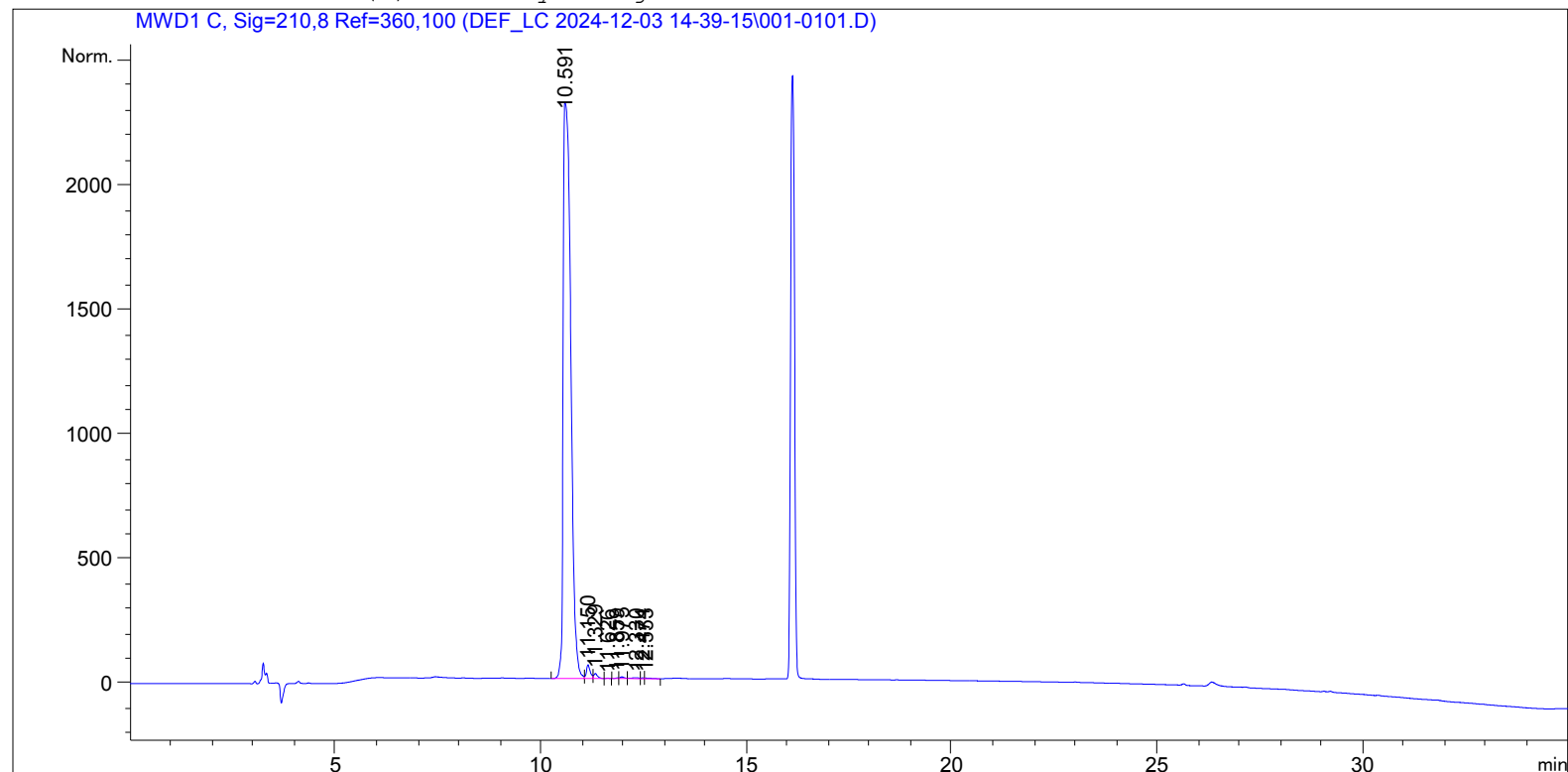
- Use the Arrhenius equation to calculate the degradation rate constants.
- Determine the activation energy ( $E_a$ ) based on the temperature and degradation rates.
- Predict time to 90% stability at **+4°C**.

#### Summary of Results:

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

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|                                               |   |                                                                           |                   |   |         |
|-----------------------------------------------|---|---------------------------------------------------------------------------|-------------------|---|---------|
| 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 |
| 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      | 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  |

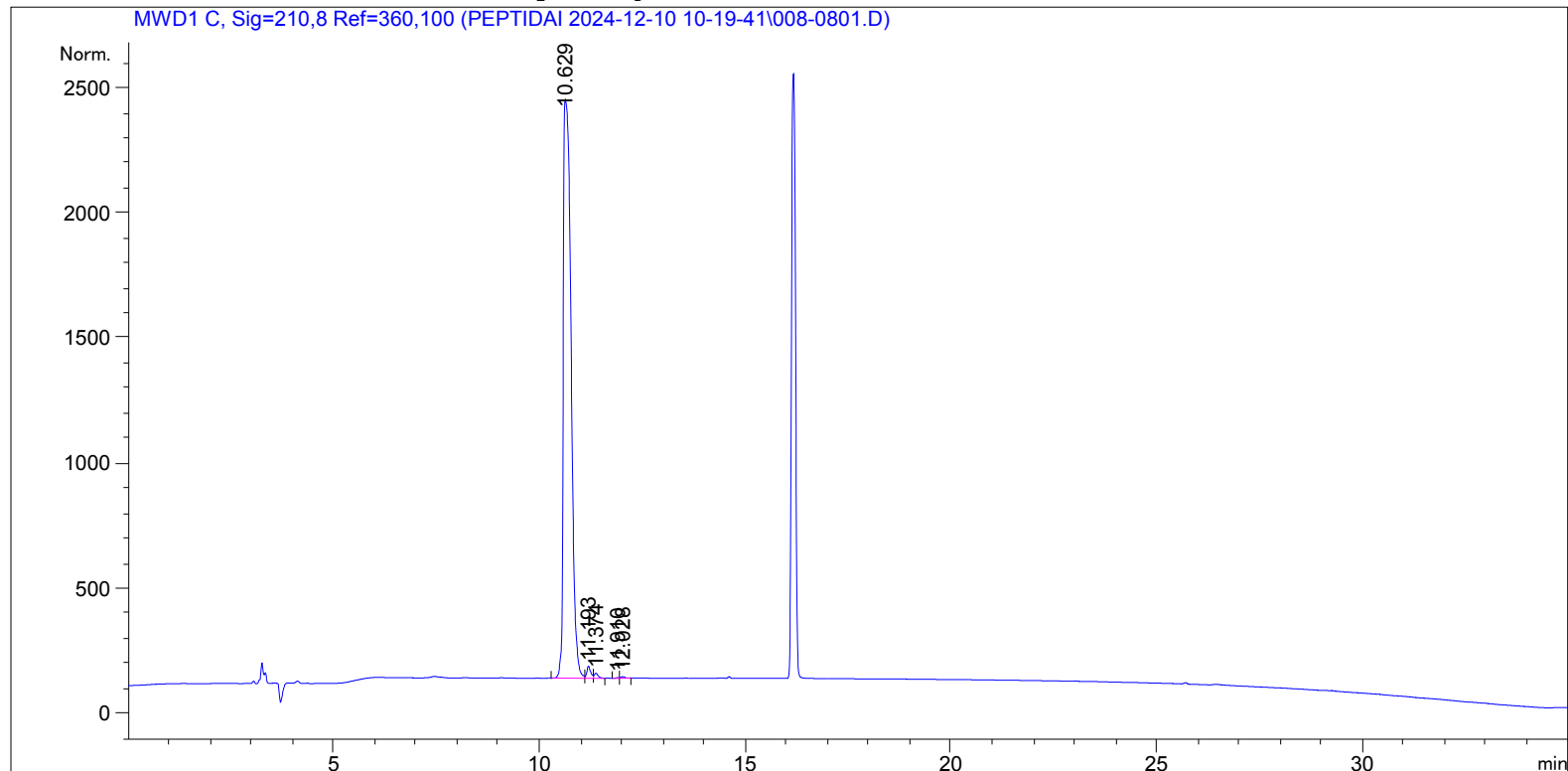
| Peak<br># | RetTime<br>[min] | Type | Width<br>[min] | Area<br>[mAU*s] | Height<br>[mAU] | Area<br>% |
|-----------|------------------|------|----------------|-----------------|-----------------|-----------|
| 9         | 12.553           | VB   | 0.1548         | 32.32976        | 2.79820         | 0.1064    |

Totals : 3.03787e4 2405.05440

\*\*\* End of Report \*\*\*

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|                                               |   |                                                                             |                   |   |         |
|-----------------------------------------------|---|-----------------------------------------------------------------------------|-------------------|---|---------|
| 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

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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      | 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

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\*\*\* End of Report \*\*\*

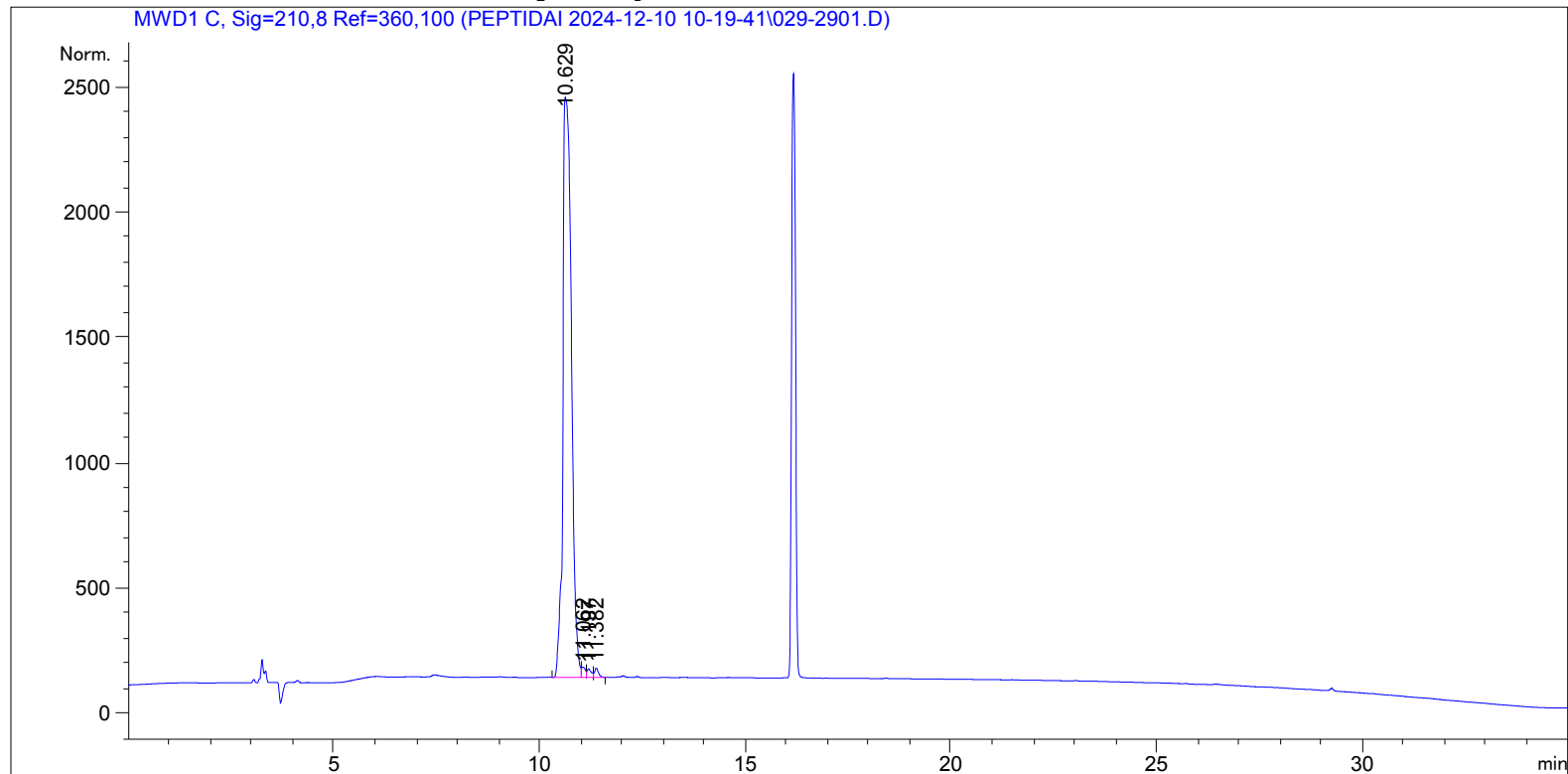
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|                 |   |                       |            |   |         |
|-----------------|---|-----------------------|------------|---|---------|
| Acq. Operator   | : |                       | Seq. Line  | : | 29      |
| Acq. Instrument | : | 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



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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      | 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  |

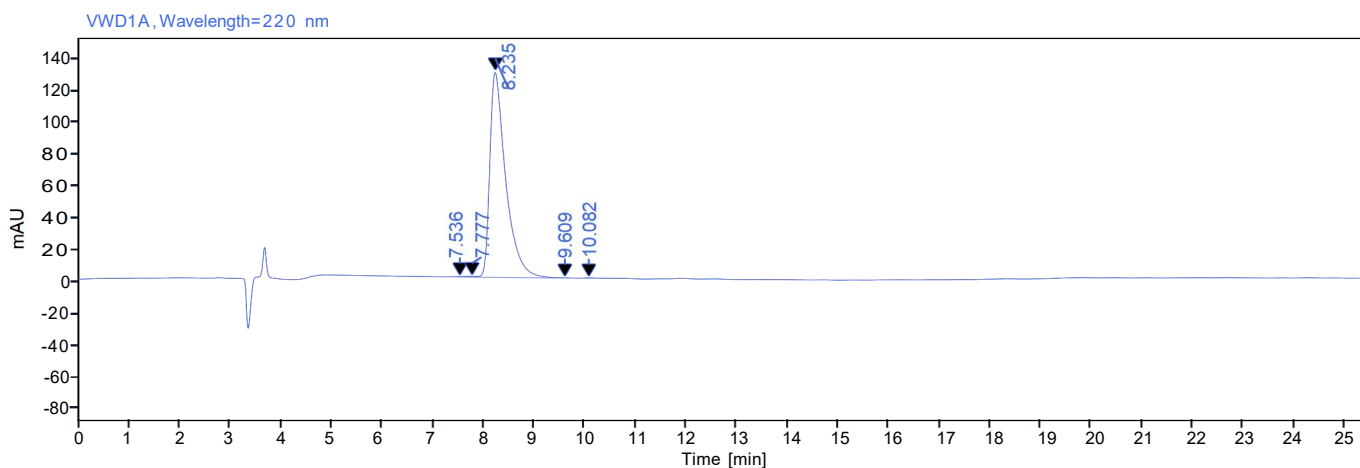
Totals :                      3.40926e4   2427.69231

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\*\*\* End of Report \*\*\*

# Single Injection Report



**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 |        |       |      |                             |

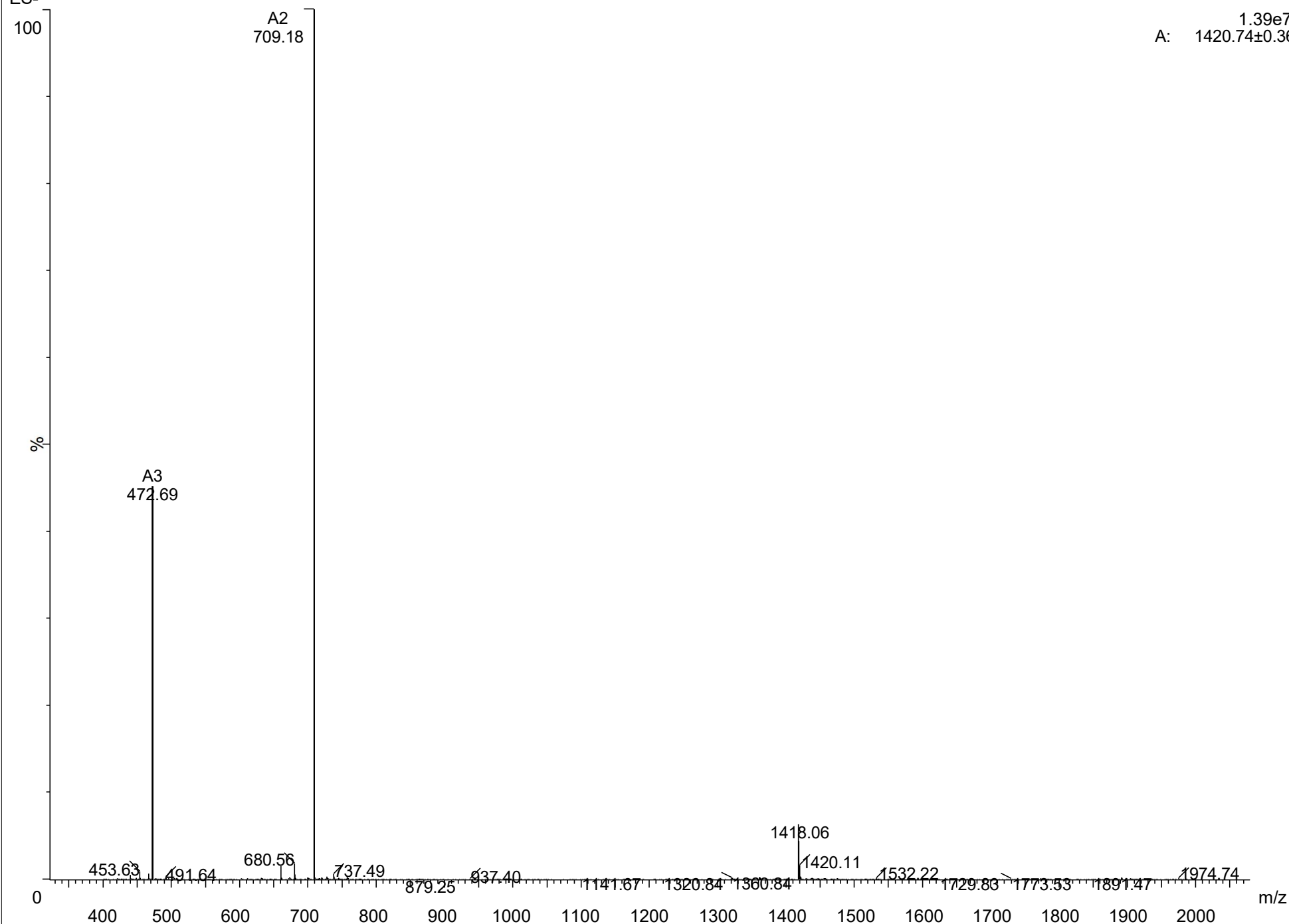
20241122-BPC157 12 (0.204) Cm (7:15)

ES-

Scan

1.39e7

A: 1420.74±0.36



# TEST REPORT



E-mail: [info@janoshik.com](mailto:info@janoshik.com)  
Web: [www.janoshik.com](http://www.janoshik.com)

Task Number #49667

Testing ordered > 20 SEP '24

Sample received > 25 SEP '24

Client Pen Peptide

Sample BPC-157

Manufacturer Unknown

Batch Unknown

Sample description >

Pictures not included.

Tests requested >

Assessment of a peptide vial or vials.

Results >



|         |          |
|---------|----------|
| BPC-157 | 10.23 mg |
| Purity  | 99.500%  |
|         |          |

Comments >

Analysis conducted > 30 SEP 2024

Signature >

Verify this test at [www.janoshik.com/verify/](http://www.janoshik.com/verify/) with the following unique key

JYBF2SE18G56