GETPEPTIDES.AE

# Pen peptide certificate of analysis (CoA)

| | | | |
|---|---|---|---|
| **Product:** | **Melanotan 2** | | |
| **Source:** | Hybrid synthesis (recombinant using peptide secretion system and chemical synthesis) | | |
| **Intended use:** | For stability, viability and activity testing only. | | |
| **Order number:** | | **Lot:** 25AUG | 05MEL |
| **Production:** | 08/2025 | **Expiry:** 08/2027 | |
| **Formulation:** | 0.2 µm-filtered solution in 20mM glycine, 200mM Mannitol, 20mM $NaH_2PO_4$, pH 7.4; m-cresol 1 mg/ml, glycerol 2 mg/ml (when liquid) | | |
| **Protein/peptide concentration per 3 ml cartridge:** | 30 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.

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# Stability report

## Melanotan 2

**Data Provided:**

- Initial concentration of Melanotan 2: **100%**.
- Concentration after 7 days at:
  - **+4°C**: **99,93%**.
  - **+42°C**: **99,93%**.

**Analysis Plan:**

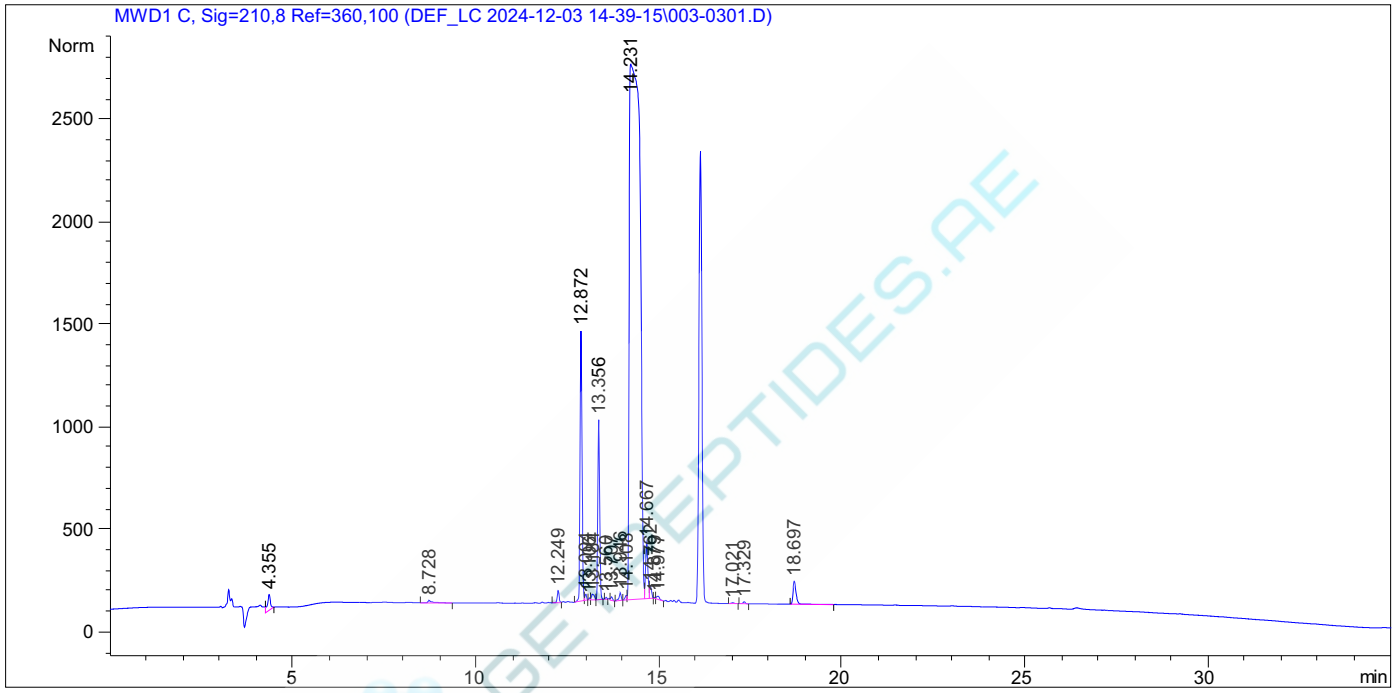
- Use the Arrhenius equation to calculate the degradation rate constants.
- Determine the activation energy (Ea) based on the temperature and degradation rates.
- Predict time to 90% stability at **+4°C**.

## Summary of Results:

- **Activation Energy (Ea)**: **10 kJ/mol**.
- **Time to 90% Stability at +4°C**: **2030 days**

Data File C:\CHEM32\1\DATA\DEF_LC 2024-12-03 14-39-15\003-0301.D
Sample Name: Melatonan 2 10mg/ml 24-12-03

```
=====================================================================
Acq. Operator   :                                Seq. Line :   3
Acq. Instrument : Instrument 1                    Location : Vial 3
Injection Date  : 12/3/2024 4:04:08 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 | 4.355 | VB | 0.0788 | 428.75476 | 77.24622 | 0.6748 |
| 2 | 8.728 | VB | 0.1367 | 119.23534 | 11.52138 | 0.1877 |
| 3 | 12.249 | BV | 0.0557 | 214.26282 | 59.93133 | 0.3372 |
| 4 | 12.872 | BV | 0.0605 | 5042.84473 | 1322.32727 | 7.9366 |
| 5 | 13.004 | VB | 0.0485 | 95.36370 | 30.51199 | 0.1501 |
| 6 | 13.106 | BV | 0.0436 | 27.53863 | 10.16362 | 0.0433 |
| 7 | 13.184 | VB | 0.0762 | 151.18065 | 27.46019 | 0.2379 |
| 8 | 13.356 | BV | 0.0556 | 3132.19092 | 879.21667 | 4.9295 |

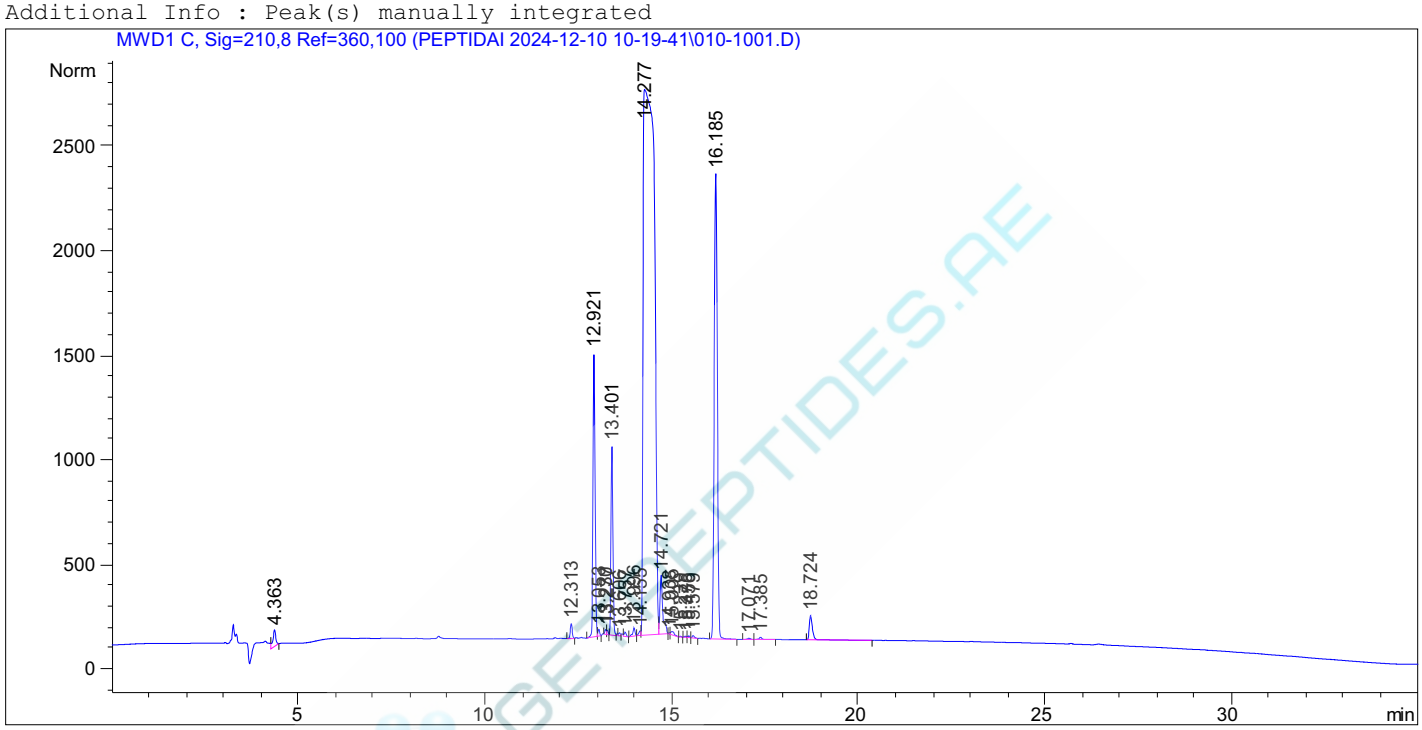
Data File C:\CHEM32\1\DATA\DEF_LC 2024-12-03 14-39-15\003-0301.D
Sample Name: Melatonan 2 10mg/ml 24-12-03

| Peak # | RetTime [min] | Type | Width [min] | Area [mAU*s] | Height [mAU] | Area % |
|---|---|---|---|---|---|---|
| 9 | 13.560 | BV | 0.0495 | 31.75516 | 9.88879 | 0.0500 |
| 10 | 13.707 | VB | 0.0549 | 62.70338 | 17.87820 | 0.0987 |
| 11 | 13.946 | BB | 0.0608 | 150.12251 | 37.44070 | 0.2363 |
| 12 | 14.108 | BV | 0.0548 | 81.29839 | 22.15911 | 0.1279 |
| 13 | 14.231 | VV | 0.2513 | 5.17661e4 | 2611.08984 | 81.4711 |
| 14 | 14.667 | VV | 0.0635 | 1170.60437 | 275.93045 | 1.8423 |
| 15 | 14.762 | VB | 0.0620 | 235.49153 | 59.75946 | 0.3706 |
| 16 | 14.879 | BV | 0.0385 | 11.43790 | 4.67971 | 0.0180 |
| 17 | 14.977 | VB | 0.0905 | 87.43967 | 15.33252 | 0.1376 |
| 18 | 17.021 | BB | 0.0700 | 22.80446 | 4.93029 | 0.0359 |
| 19 | 17.329 | BB | 0.0657 | 40.74974 | 9.56350 | 0.0641 |
| 20 | 18.697 | VV | 0.0889 | 667.35626 | 113.03426 | 1.0503 |
| Totals : | | | | 6.35392e4 | 5600.06549 | |

*** End of Report ***

Data File C:\CHEM32\1\DATA\PEPTIDAI 2024-12-10 10-19-41\010-1001.D
Sample Name: Melatonan 2 10mg/ml 4C 24-12-10

```
==========================================================================
Acq. Operator   :                                    Seq. Line :  10
Acq. Instrument : Instrument 1                        Location : Vial 10
Injection Date  : 12/10/2024 4:33:57 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\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
```






```
==========================================================================
                          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 | 4.363 | VB | 0.0780 | 416.19717 | 78.34694 | 0.5303 |
| 2 | 12.313 | BV | 0.0556 | 253.09528 | 70.97786 | 0.3225 |
| 3 | 12.921 | BV | 0.0617 | 5332.77295 | 1360.19507 | 6.7947 |
| 4 | 13.053 | VB | 0.0488 | 101.30499 | 32.12597 | 0.1291 |
| 5 | 13.230 | BV | 0.0441 | 62.10098 | 21.24787 | 0.0791 |
| 6 | 13.277 | VB | 0.0437 | 55.40018 | 20.41612 | 0.0706 |
| 7 | 13.401 | BV | 0.0587 | 3313.25659 | 906.30316 | 4.2216 |
| 8 | 13.606 | VV | 0.0581 | 57.50664 | 14.55860 | 0.0733 |

Data File C:\CHEM32\1\DATA\PEPTIDAI 2024-12-10 10-19-41\010-1001.D
Sample Name: Melatonan 2 10mg/ml 4C 24-12-10

| Peak # | RetTime [min] | Type | Width [min] | Area [mAU*s] | Height [mAU] | Area % |
|---|---|---|---|---|---|---|
| 9 | 13.757 | VB | 0.0579 | 75.45711 | 20.03699 | 0.0961 |
| 10 | 13.996 | BB | 0.0624 | 160.93283 | 38.78497 | 0.2051 |
| 11 | 14.155 | BV | 0.0551 | 79.47566 | 21.49830 | 0.1013 |
| 12 | 14.277 | VV | 0.2560 | 5.32399e4 | 2609.27515 | 67.8354 |
| 13 | 14.721 | VB | 0.0765 | 1466.48157 | 282.76068 | 1.8685 |
| 14 | 14.938 | BV | 0.0331 | 10.95662 | 5.09542 | 0.0140 |
| 15 | 15.005 | VB | 0.0919 | 104.54166 | 14.90004 | 0.1332 |
| 16 | 15.239 | BB | 0.0497 | 10.59188 | 3.46175 | 0.0135 |
| 17 | 15.375 | BV | 0.0575 | 22.18423 | 5.95004 | 0.0283 |
| 18 | 15.456 | VB | 0.0545 | 25.07720 | 7.22376 | 0.0320 |
| 19 | 15.579 | BB | 0.0616 | 45.50474 | 11.15349 | 0.0580 |
| 20 | 16.185 | BB | 0.0935 | 1.28752e4 | 2225.41187 | 16.4049 |
| 21 | 17.071 | VV | 0.0770 | 27.70311 | 5.29725 | 0.0353 |
| 22 | 17.385 | VV | 0.0831 | 58.86740 | 10.54869 | 0.0750 |
| 23 | 18.724 | VV | 0.0870 | 689.44879 | 116.64630 | 0.8785 |
| Totals : | | | | 7.84839e4 | 7882.21627 | |

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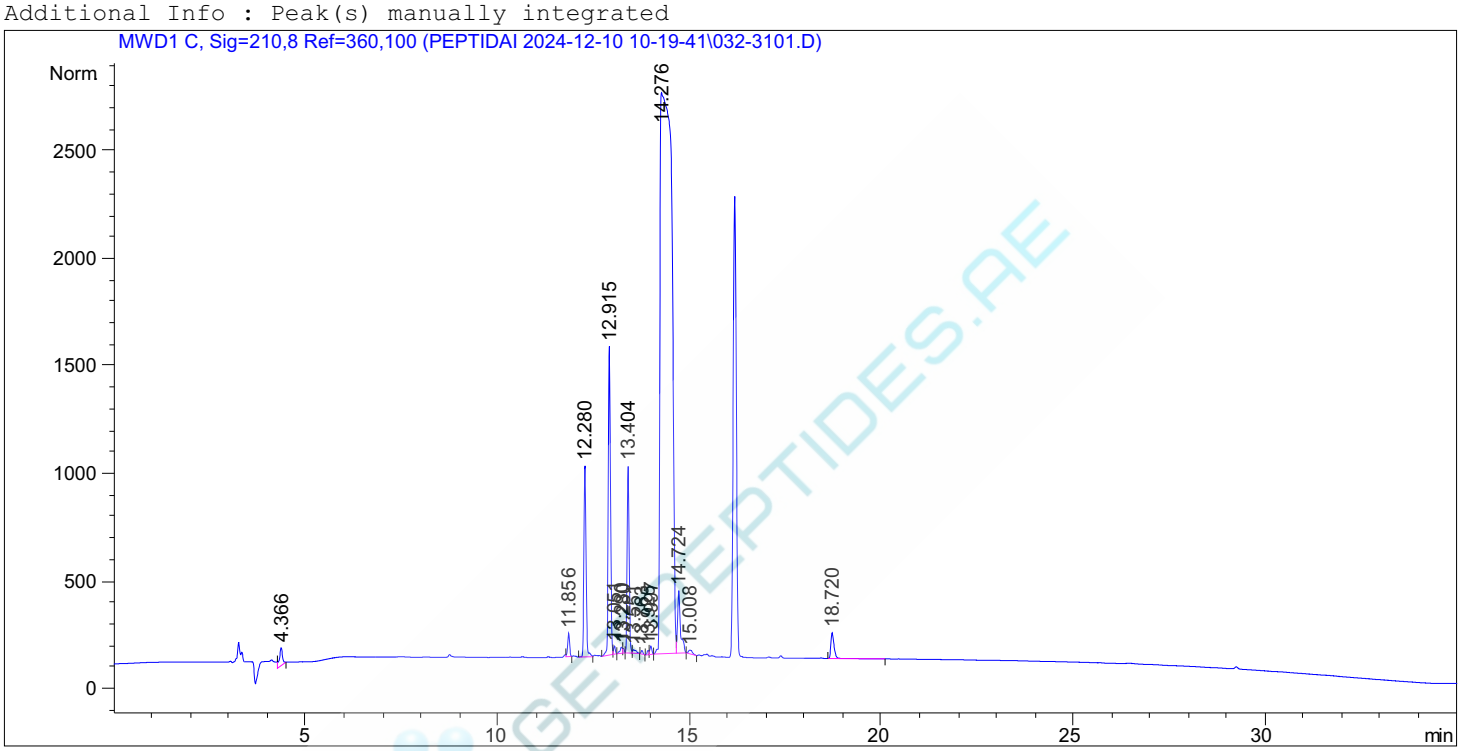
*** End of Report ***

Data File C:\CHEM32\1\DATA\PEPTIDAI 2024-12-10 10-19-41\032-3101.D
Sample Name: Melatonan 2 10mg/ml 42C 24-12-10

```
==========================================================================
Acq. Operator   :                                   Seq. Line :  31
Acq. Instrument : Instrument 1                       Location : Vial 32
Injection Date  : 12/11/2024 7:06:39 AM                   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\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 3:15:57 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 | 4.366 | VB | 0.0803 | 456.91794 | 82.89652 | 0.6501 |
| 2 | 11.856 | VB | 0.0554 | 388.57358 | 109.57032 | 0.5529 |
| 3 | 12.280 | BV | 0.0620 | 3511.80908 | 889.73138 | 4.9969 |
| 4 | 12.915 | BV | 0.0629 | 5772.88574 | 1435.58496 | 8.2141 |
| 5 | 13.051 | VB | 0.0516 | 122.11559 | 37.84670 | 0.1738 |
| 6 | 13.230 | BV | 0.0632 | 123.85581 | 28.22560 | 0.1762 |
| 7 | 13.280 | VB | 0.0426 | 56.59282 | 21.55673 | 0.0805 |
| 8 | 13.404 | BV | 0.0589 | 3206.44092 | 872.96228 | 4.5624 |

Data File C:\CHEM32\1\DATA\PEPTIDAI 2024-12-10 10-19-41\032-3101.D
Sample Name: Melatonan 2 10mg/ml 42C 24-12-10

| Peak # | RetTime [min] | Type | Width [min] | Area [mAU*s] | Height [mAU] | Area % |
|---|---|---|---|---|---|---|
| 9 | 13.551 | VB | 0.0848 | 103.88914 | 16.20423 | 0.1478 |
| 10 | 13.763 | BB | 0.0527 | 55.15992 | 16.61440 | 0.0785 |
| 11 | 13.925 | BV | 0.0486 | 60.95539 | 19.44437 | 0.0867 |
| 12 | 13.997 | VB | 0.0555 | 138.68478 | 39.01685 | 0.1973 |
| 13 | 14.276 | BV | 0.2591 | 5.39256e4 | 2609.48389 | 76.7294 |
| 14 | 14.724 | VB | 0.0777 | 1546.17273 | 292.59558 | 2.2000 |
| 15 | 15.008 | BB | 0.1013 | 128.09209 | 16.73544 | 0.1823 |
| 16 | 18.720 | BB | 0.0867 | 682.50165 | 119.38790 | 0.9711 |
| Totals : | | | | 7.02802e4 | 6607.85714 | |

*** End of Report ***

# REPORT

Product Name:Melanotan 2

Instrument No: 0200047

Lot No :20250805

Column :4.6*250mm,kromasil C18-5

Solvent A :0.1%Trifluoroacetic in 100% Acetonitrile

Solvent B :0.1%Trifluoroacetic in 100% Water

Gradient :

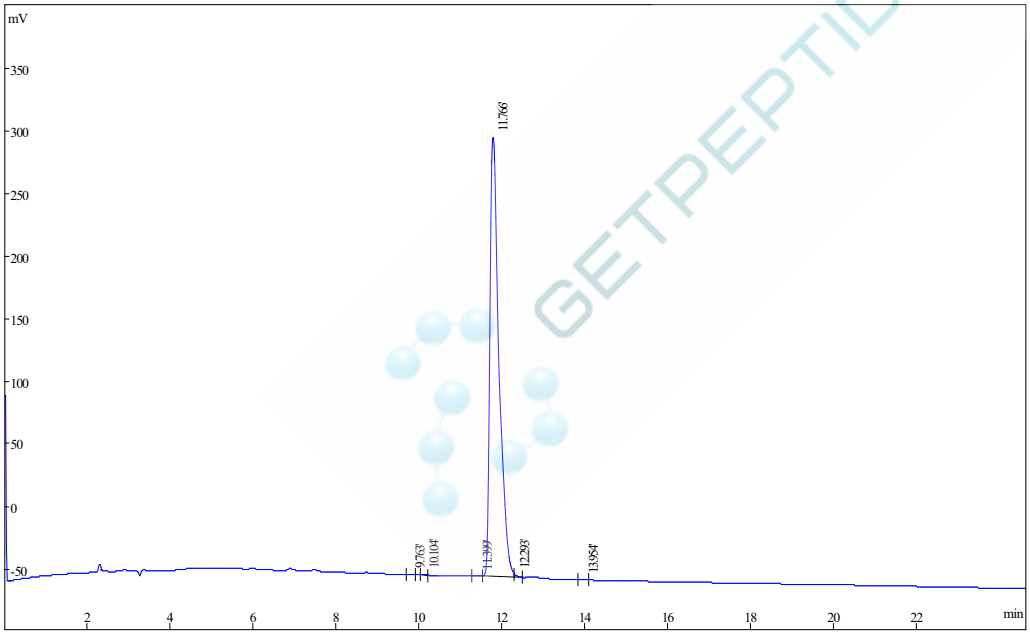
| | A | B |
|---|---|---|
| 0.01min | 30% | 70% |
| 25min | 55% | 45% |
| 25.1min | 100% | 0% |
| 30min | Stop | |

Flow rate :1.0ml/min

Wavelength :220nm

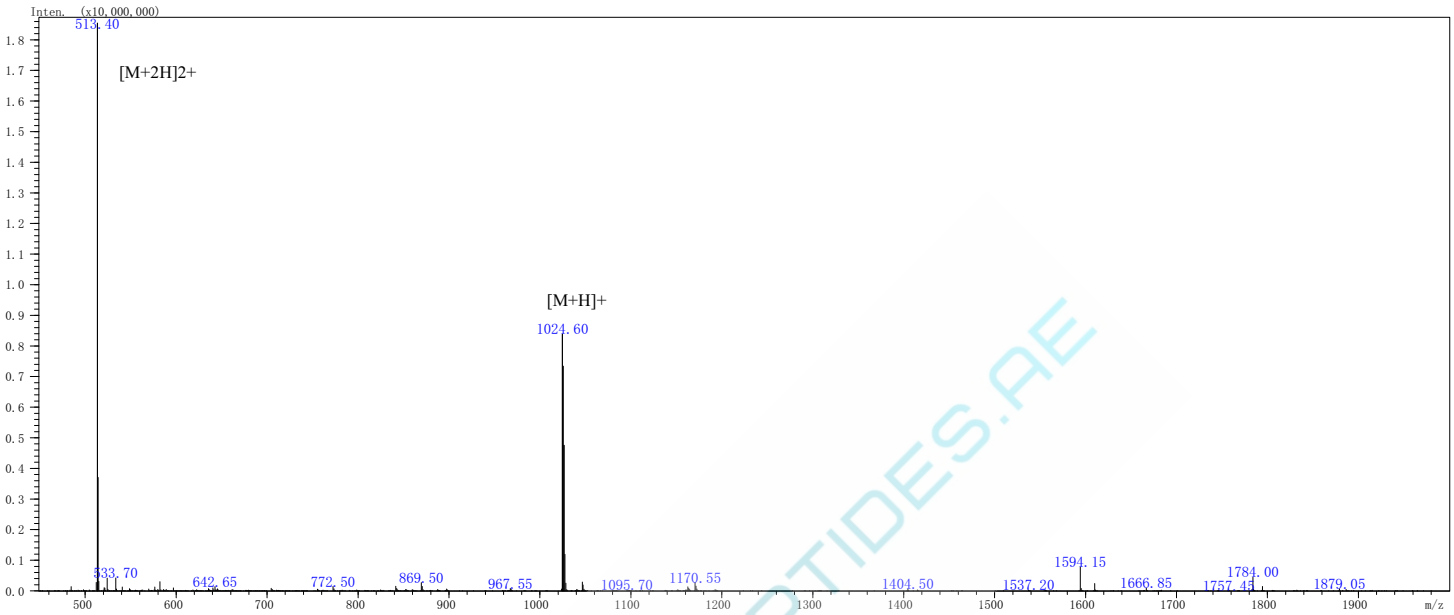
Volume:5ul

File opened: F:\ 477171-30-55.hw, where




| Rank | Time | Conc. | Area | Height |
|---|---|---|---|---|
| 1 | 9.763 | 0.0465 | 2310 | 302 |
| 2 | 10.104 | 0.03982 | 1978 | 316 |
| 3 | 11.399 | 0.2248 | 6199 | 505 |
| 4 | 11.766 | 99.27 | 4945535 | 350988 |
| 5 | 12.293 | 0.2347 | 6690 | 1937 |
| 6 | 13.954 | 0.08226 | 4086 | 463 |
| Total | | 100 | | |

# MASS SPECTROMETRY REPORT




| | | | | | |
|---|---|---|---|---|---|
| Sample Description | | Instrument | SHIMADZU LCMS-2020 | | |
| Analyzed date: | 2025/08/05 | Probe: | ESI | Probe Bias: | +4.5kv |
| Analyst: | PY | Nebulizer Gas Flow: | 1.5L/min | Detector: | 1.2kv |
| Sample: | Melanotan 2 | CDL: | -20.0v | T. Flow: | 0.2ml/min |
| M.W.: | 1024.20 | CDL Temp.: | 250 ℃ | B. Conc.: | 50%H2O/50%ACN |
| Lot. No.: | 20240620 | Block Temp.: | 400 ℃ | | |