

Pen peptide certificate of analysis (CoA)

Product:	Melitin
Source:	Hybrid synthesis (recombinant using peptide secretion system and chemical synthesis)
Intended use:	For stability, viability and activity testing only.
Order number:	Lot: 25AUG18MEL
Production: 08/2025	Expiry: 08/2027
Formulation:	0.2 µm-filtered solution in 20mM glycine, 200mM Mannitol, 20mM NaH ₂ PO ₄ , pH 5.4; 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 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.

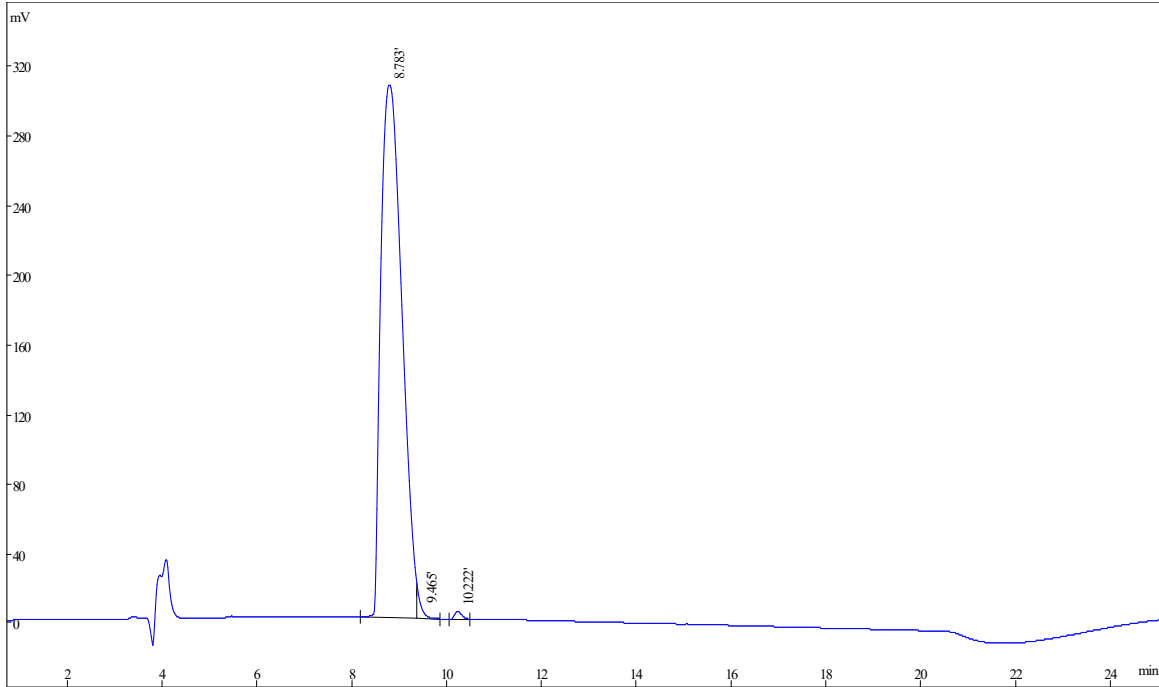
Storage and stability: Store material at +2 - +8°C. **Do not freeze!**

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.

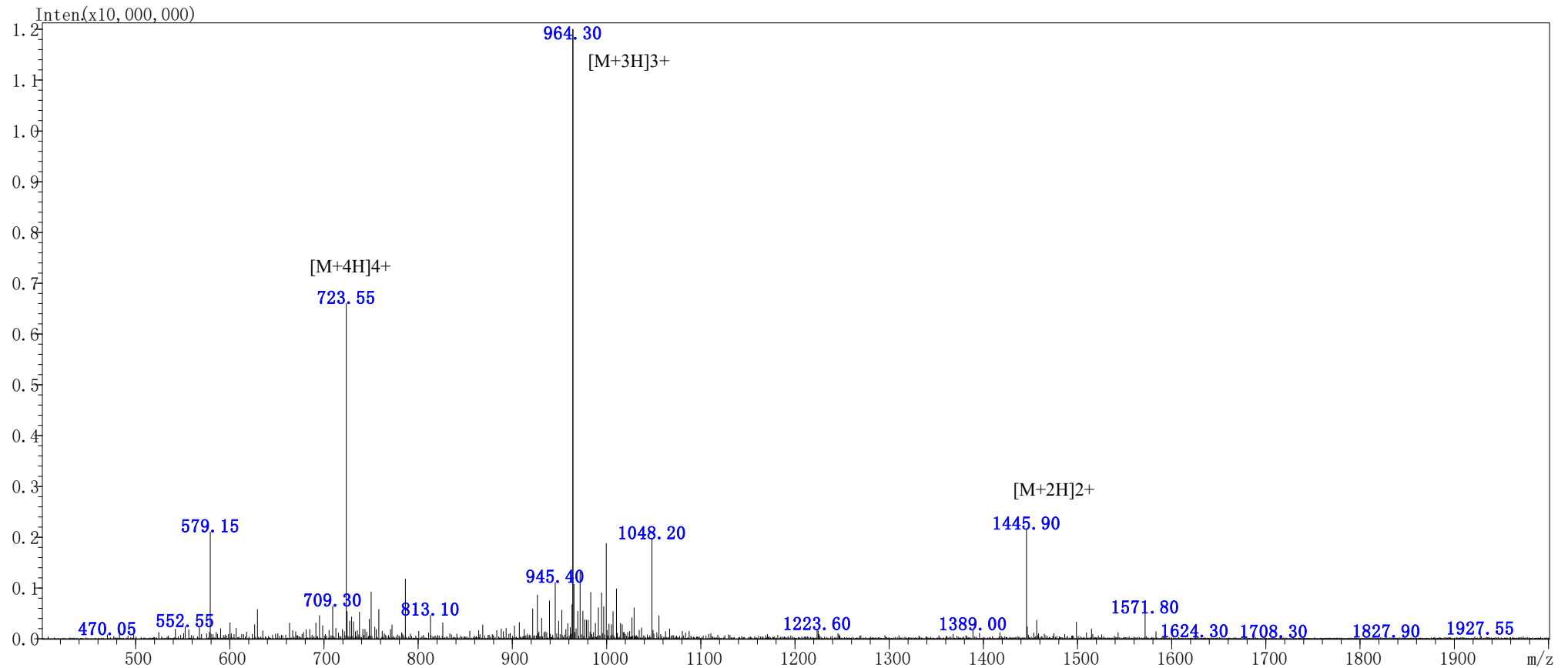
HPLC REPORT

Sample: Melittin Analyzed Time: 2025-08-18 13:13
Analyst: LJJ
Lot No.: 20250818
Column: Symmetrix ODS-R, 4.6*250mm, 5µm
Solvent A: A: 0.1% Trifluoroacetic Acid in 100% Acetonitrile
Solvent B: B: 0.1% Trifluoroacetic Acid in 100% Water
Gradient :
0.0min 44% 56%
25.0min 69% 31%
25.1min 100% 0%
30.0min Stop
Volume: 10µl
Wavelength: 220nm
Flow rate: 1.0ml/min



Rank	Time	Conc.	Area	Height
1	8.783	98.65	9153681	305720
2	9.465	0.879	81561	5133
3	10.222	0.4683	43452	4664
Total		100	9278694	315517

MASS SPECTROMETRY REPORT



Sample Description

Analyzed date: 2025/08/18

Analyst: PY

Sample: Melittin

M.W.: 2889.48

Lot. No.: 20250818

Instrument

Probe:

Nebulizer Gas Flow: 1.5L/min

CDL:

CDL Temp.: 250 °C

Block Temp.: 400 °C

SHIMADZU LCMS-2020

ESI

-20.0v

Probe Bias:

Detector:

T. Flow:

B. Conc.:

+4.5kv

1.2kv

0.2ml/min

50%H2O/50%ACN