

Pen peptide certificate of analysis (CoA)

Product:	Prostamax
Source:	Hybrid synthesis (recombinant using peptide secretion system and chemical synthesis)
Intended use:	For stability, viability and activity testing only.
Order number:	Lot: 25AUG25PRO
Production: 08/2025	Expiry: 08/2027
Formulation:	0.2 µm-filtered solution in 20mM glycine, 200mM Mannitol, 20mM NaH ₂ PO ₄ , pH 5.3; m-cresol 1 mg/ml, glycerol 2 mg/ml (when liquid)
Protein/peptide concentration per 3 ml cartridge:	30 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.

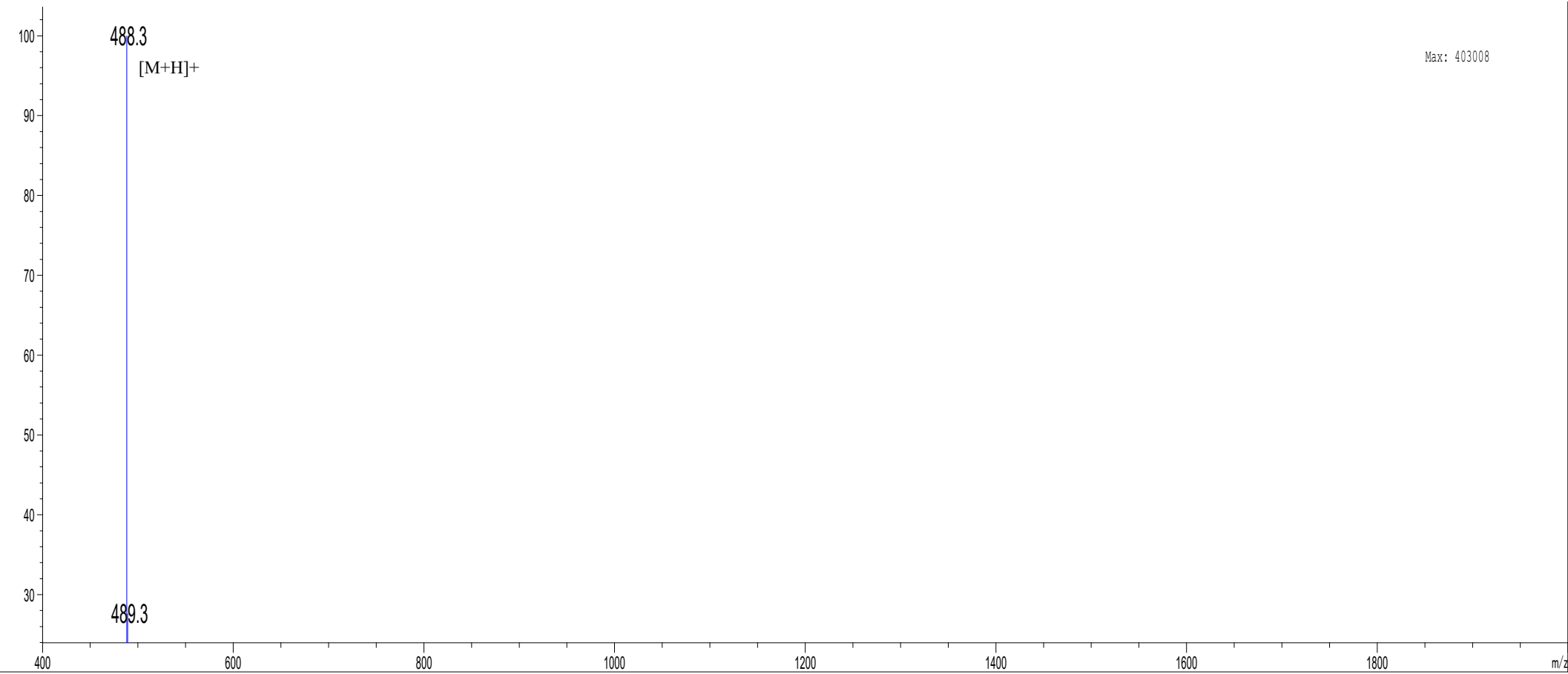
Using liquid product: Liquid products are ready to use according to physician recommendations.

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.

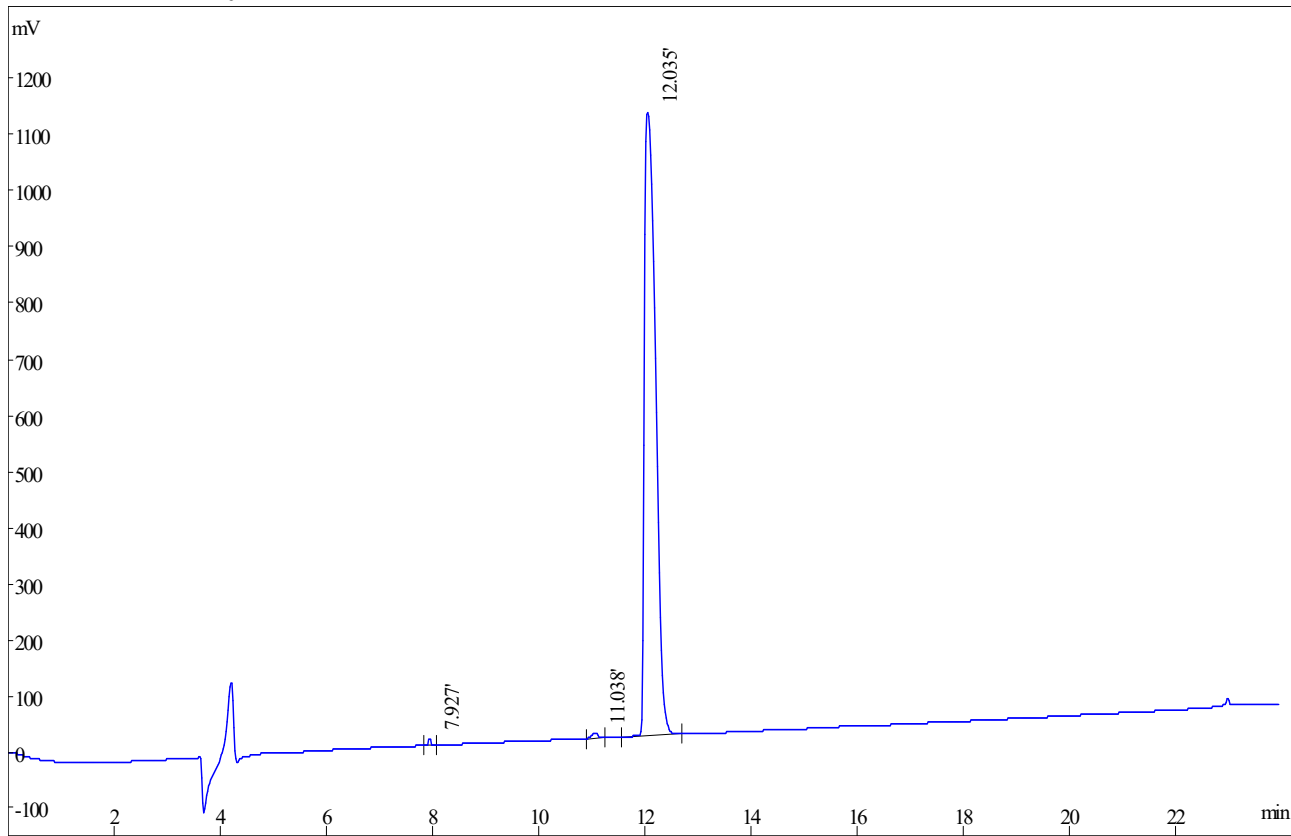
MASS SPECTROMETRY REPORT



Sample Description		Instrument		Agilent-6125B	
Analyzed date:	2025-08-25	Probe:	ESI	Probe Bias:	+4.5kv
Analyst:	YU	Nebulizer Gas Flow:	1.5L/min	Detector:	1.5kv
Sample:	Prostamax	CDL:	-20.0v	T. Flow:	0.2ml/min
M.W.:	487.5	CDL Temp.:	250 °C	B. Conc.:	50%H2O/50%ACN
Lot. No.:	20250825	Block Temp.:	200 °C		

HPLC REPORT

Sample: Prostamax Analyzed date: 2025-08-25
Analyst: HCM
Lot. No.: 20250825
Column: 4.6×250mm, SinoChrom ODS-BP
Solvent A: A: 0.1% Trifluoroacetic Acid in 100% Acetonitrile
Solvent B: B: 0.1% Trifluoroacetic Acid in 100% Water
Gradient:
0.0min 5% 95%
25.0min 30% 70%
25.1min 100% 0%
30.0min Stop
Volume: 5µl
Wavelength: 220nm
Flow rate: 1.0ml/min



Rank	Time	Conc.	Area	Height
1	7.927	0.1516	22961	10765
2	11.038	0.4181	63311	9870
3	12.035	99.43	15056643	1108172
Total		100	15142915	1128807