

## Pen peptide certificate of analysis (CoA)

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

<b>Release Testing:</b>	<b>Specification</b>	<b>Lot Result</b>
<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 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.

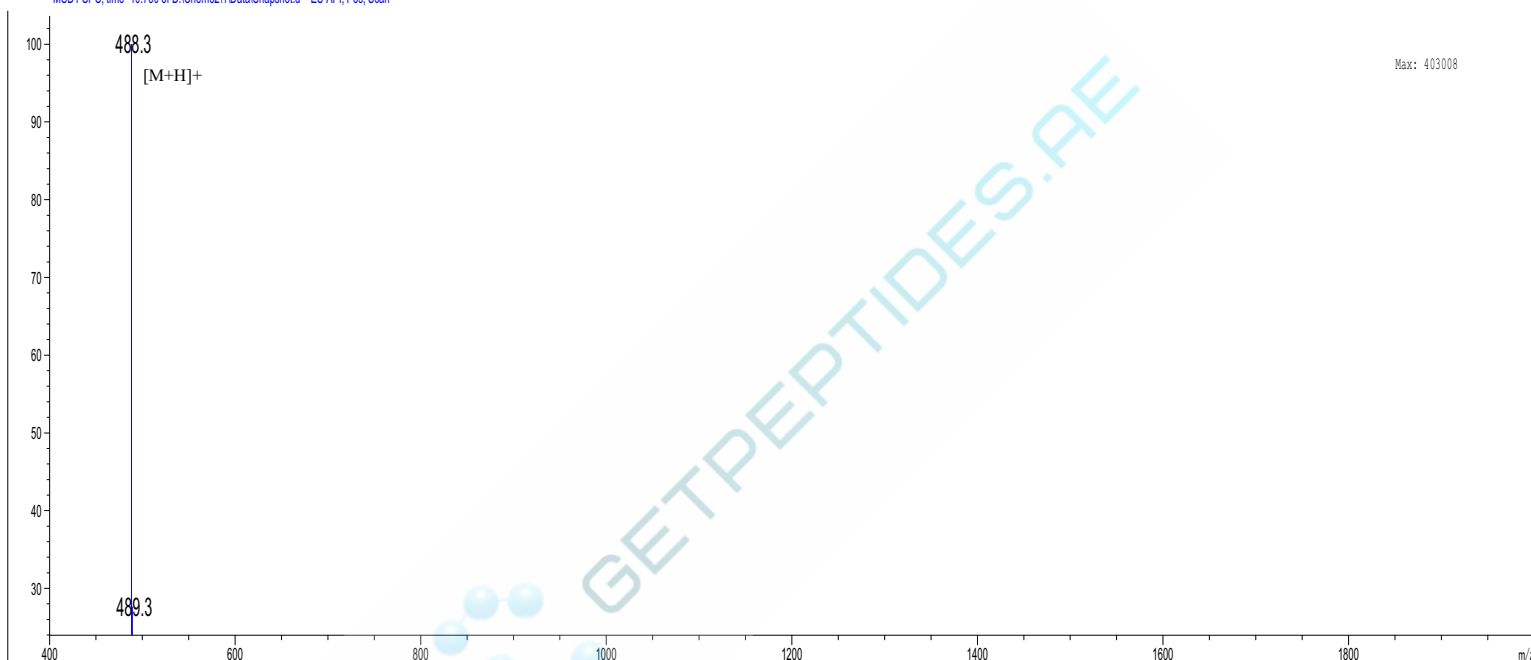
**Storage and stability:** Store material at +2 - +8°C. **Do not freeze!**

### **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

\*MSD1 SPC, time=10.780 of D:\Chem32\11\Data\Snapsho1.d ES-API, Pos, Scan



## Sample Description

Analyzed date: 2025-08-25  
Analyst: YU  
Sample: Prostamax  
M.W.: 487.5  
Lot. No.: 20250825

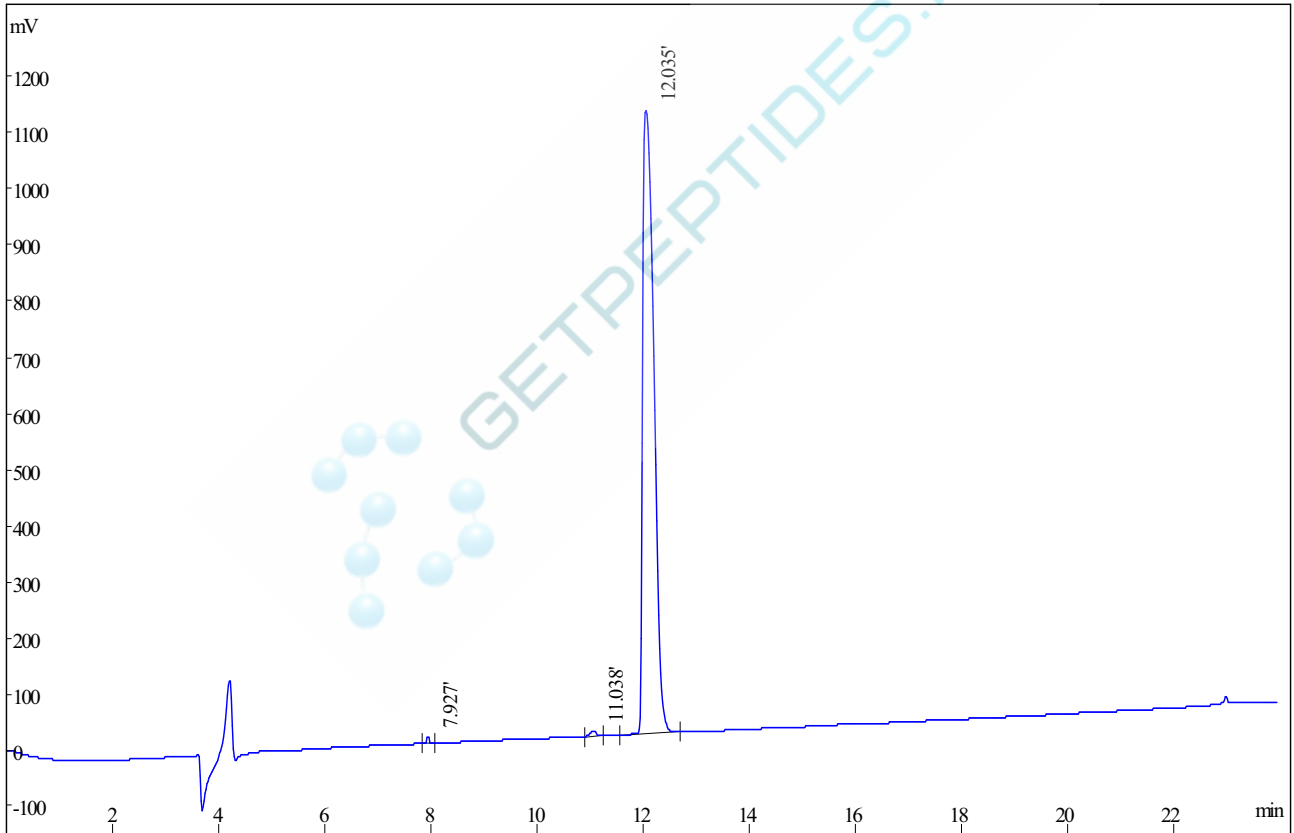
## Instrument

Agilent-6125B  
Probe: ESI  
Nebulizer Gas Flow: 1.5L/min  
CDL: -20.0v  
CDL Temp.: 250 °C  
Block Temp.: 200 °C

Probe Bias: +4.5kv  
Detector: 1.5kv  
T. Flow: 0.2ml/min  
B. Conc.: 50%H2O/50%ACN

# 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 A 5% B 95%  
25.0min A 30% B 70%  
25.1min A 100% B 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