

Pen peptide certificate of analysis (CoA)

Product:	AC-SEMAX-NH2		
Source:	Hybrid synthesis (recombinant using peptide secretion system and chemical synthesis)		
Intended use:	For stability, viability and activity testing only.		
Order number:		Lot: 25AUG	25MAX
Production:	08/2025	Expiry:	08/2027
Formulation:	0.2 µm-filtered solution in 20mM glycine, 200mM Mannitol, 20mM NaH ₂ PO ₄ , pH 5.6; 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.

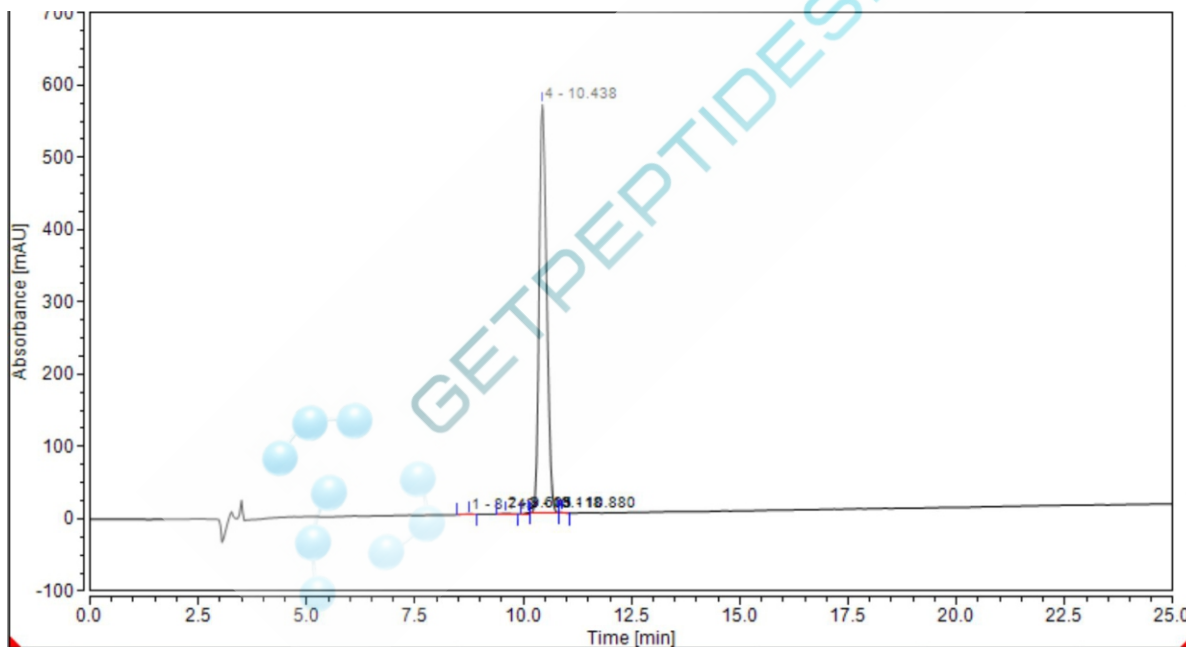
Storage and stability: Store material at +2 - +8°C. **Do not freeze!**

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.

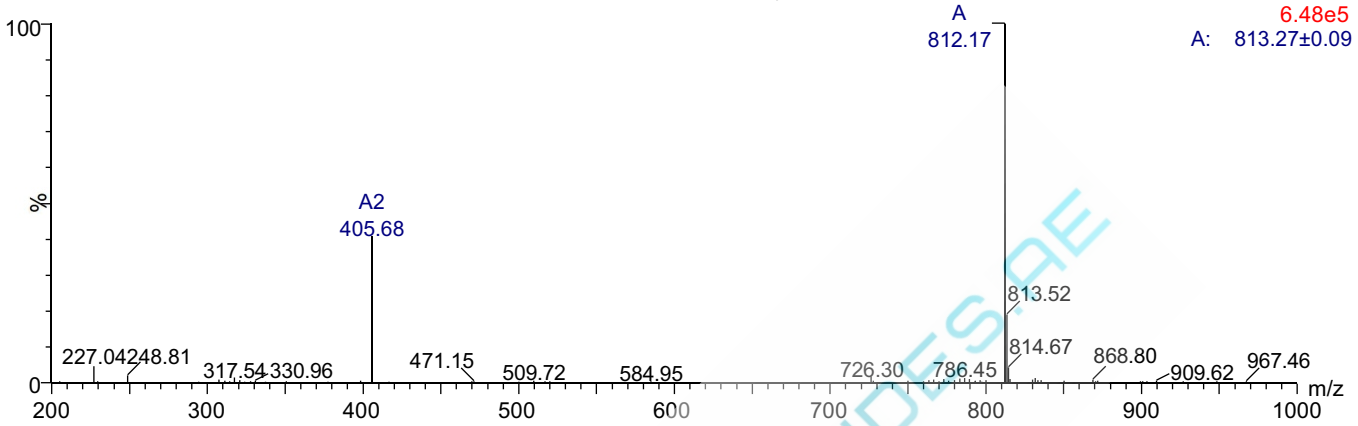
Sample Information

Product Name : Semax
 Lot. No : 202508
 Sequence : Met-Glu-His-Phe-Pro-Gly-Pro
 Column : Welch, XB-C18, (4.6mm i.d., 250 mm L)
 Buffer : A: 0.1% TFA in Acetonitrile B: 0.1% TFA in H2O
 Gradient : 15-40% in 25min
 Flow rate : 1.0ml/min
 Wavelength : 220nm
 Dissolution method : 100% H2O
 Injection date : 21/08/2025 11:27:33 AM



Integration Results							
No.	Peak Name	Retention Time min	Area mAU*min	Height mAU	Relative Area %	Relative Height %	Amount n.a.
1		8.743	0.167	0.681	0.15	0.12	n.a.
2		9.603	0.184	0.718	0.16	0.13	n.a.
3		10.118	0.156	1.404	0.14	0.25	n.a.
4		10.438	113.859	565.913	99.41	99.30	n.a.
5		10.880	0.165	1.180	0.14	0.21	n.a.
Total:			114.532	569.896	100.00	100.00	

MS Spectrum



Dissolution :0.1%HCOOH+ACN
Date :2025/08/21 15:59:45
Injection :2.5ul
Block Temp :150

Interface :ESI
Nebulizing Gas Flow :500L/hr
CDL Temp :400C
CDL Volt :-15v

Prerod Bias :+3.5kv
Detector :-0.2kv
T.Flow :0.35ml/min
B.conc :50%H2O/50%MEOH

Product Name : Semax
Sequence : MEHFPGP
Lot.No : 2508
Theoretical : 813.92
Observed : 813.36



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