

## Pen peptide certificate of analysis (CoA)

<b>Product:</b>	<b>SS-31</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>	25AUG25SS3
<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 5.7; 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.

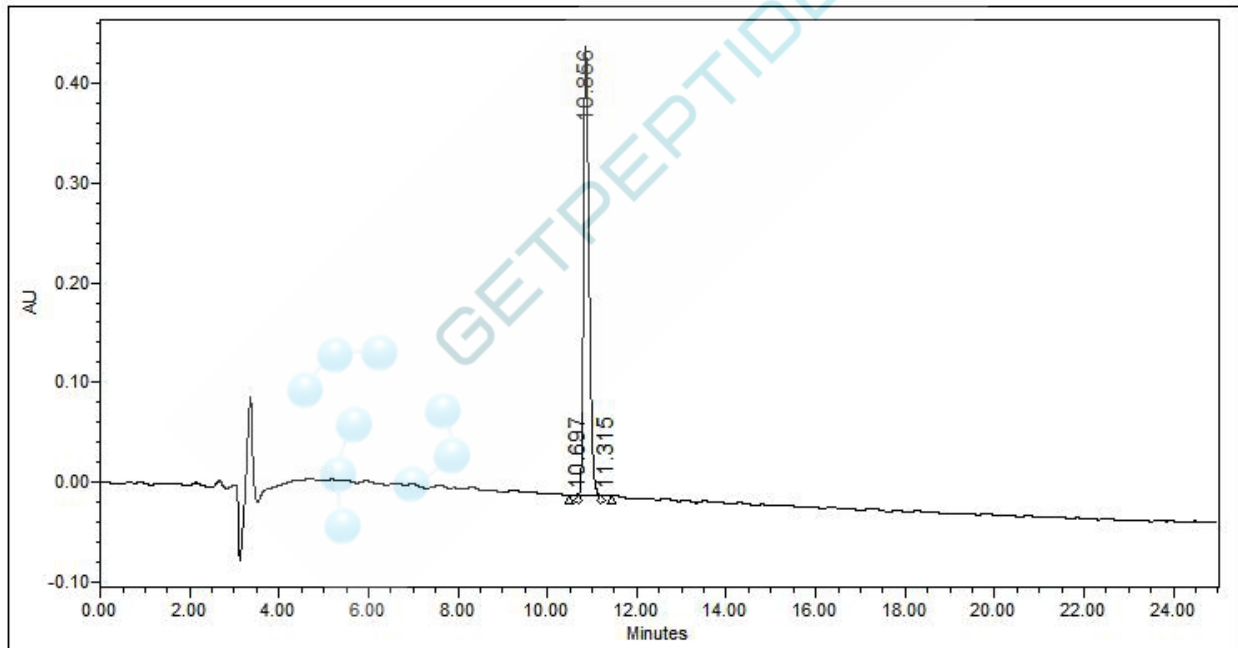
**Storage and stability:** Store material at +2 - +8°C. **Do not freeze!**

### **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.

## Sample Information

Product Name :Elamipretide, SS-31  
Lot. No :20250825  
Sequence :D-Arg-dimethylTyr-Lys-Phe-NH2  
Column : Kromasil, 100-5-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 25 min  
Flow rate :1.0ml/min  
Wavelength :220nm  
Dissolution method :100%H2O



RT	Area	% Area	Height
10.697	9604	0.25	1716
10.856	3903365	99.58	451822
11.315	6740	0.17	721

P240308-L004 11 (0.187) Cm (10:18)

MS Spectrum

Scan ES+  
8.06e6



Dissolution	:0.1%HCOOH+ACN	Interface	:ESI	Prerod Bias	:+3.5kv
Date	:2025/08/25 19:31:31	Nebulizing Gas Flow	:500L/hr	Detector	:-0.2kv
Injection	:2.5ul	CDL Temp	:400C	T.Flow	:0.35ml/min
Block Temp	:150	CDL Volt	:+15v	B.conc	:50%H2O/50%MEOH

Product Name : Elamipretide, SS-31  
Sequence : D-Arg-dimethylTyr-Lys-Phe-NH2  
Lot.No : 20250825  
Theoretical : 639.80  
Observed : 639.70