

Pen peptide certificate of analysis (CoA)

Product: SS-31
Source: Hybrid synthesis (recombinant using peptide secretion system and chemical synthesis)
Intended use: For stability, viability and activity testing only.
Order number: **Lot:** 25AUG25SS3
Production: 08/2025 **Expiry:** 08/2027
Formulation: 0.2 µm-filtered solution in 20mM glycine, 200mM Mannitol, 20mM NaH₂PO₄, pH 5.7; 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 a Nb2-11 cell proliferation assay.
 Purity was determined by SDS PAGE and coomassie stain (under reducing and non-reducing conditions).
 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 was determined using fluorimetric assay.

Handling Instructions:

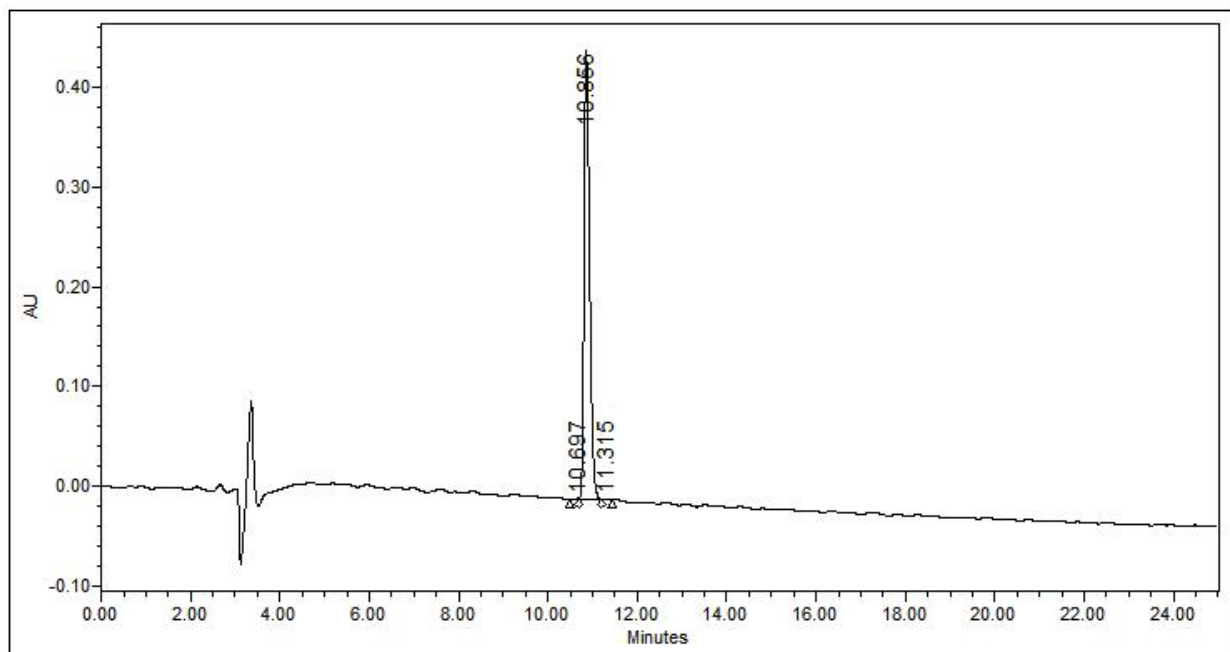
General usage: Open cap, clean the rubber stopper with disinfectant napkin or other cleaning disinfection method / material. Puncture rubber stopper with sterile needle by screwing needle on. Remove the plastic protective cover. Set the index to physician prescribed position, remove the pink plastic 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

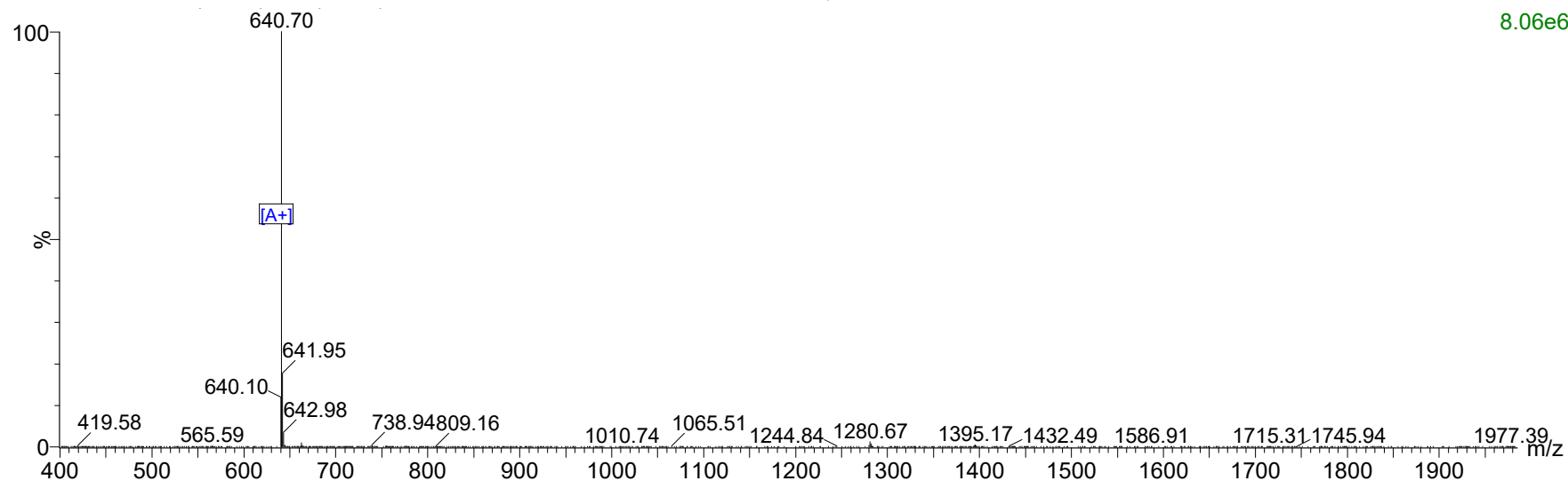
Product Name :Elamipretide, SS-31
 Lot. No :20250825
 Sequence :D-Arg-dimethylTyr-Lys-Phe-NH2
 Column : Kromasil, 100-5-C18,(4.6mm i.d.,250 mm L)
 Buffer : A: 0.1% TFA in Acetonitrile B: 0.1% TFA in H2O
 Gradient :15-40% in 25 min
 Flow rate :1.0ml/min
 Wavelength :220nm
 Dissolution method :100%H2O



	RT	Area	% Area	Height
1	10.697	9604	0.25	1716
2	10.856	3903365	99.58	451822
3	11.315	6740	0.17	721

MS Spectrum

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