

Pen peptide certificate of analysis (CoA)

Product:	Thymosin alpha 1		
Source:	Hybrid synthesis (recombinant using peptide secretion system and chemical synthesis)		
Intended use:	For stability, viability and activity testing only.		
Order number:		Lot:	25AUG15ALP
Production:	08/2025	Expiry:	08/2027
Formulation:	0.2 µm-filtered solution in 20mM glycine, 200mM Mannitol, 20mM NaH ₂ PO ₄ , pH 7.4; 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.

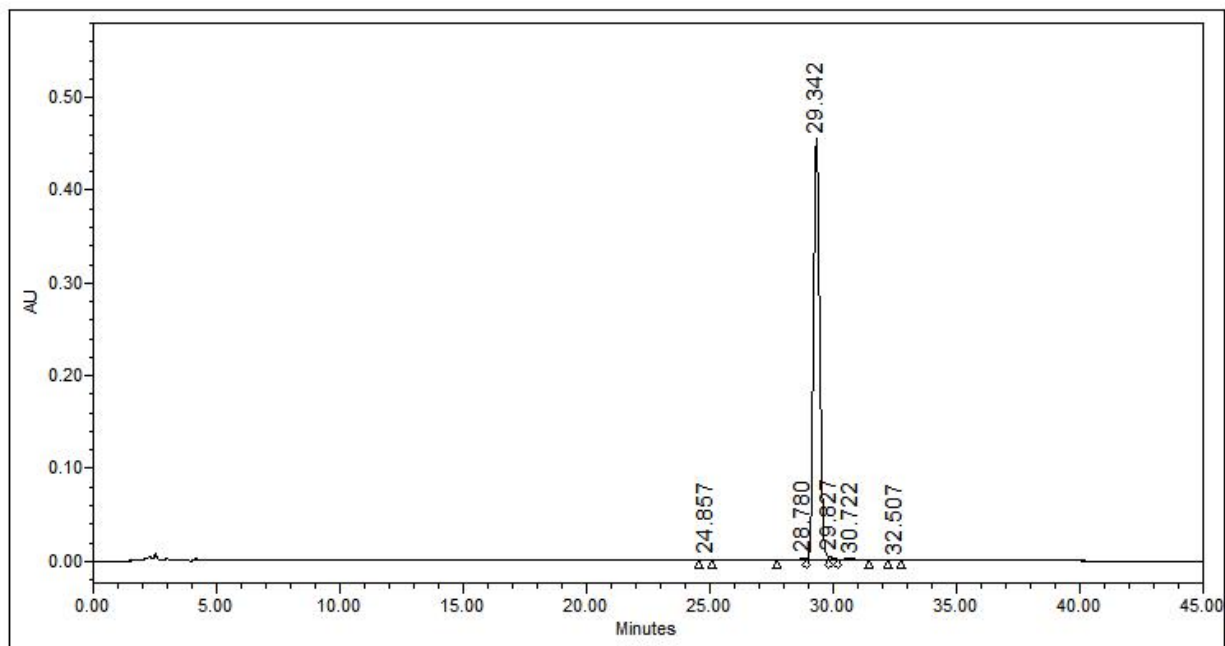
Storage and stability: Store material at +2 - +8°C. **Do not freeze!**

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.

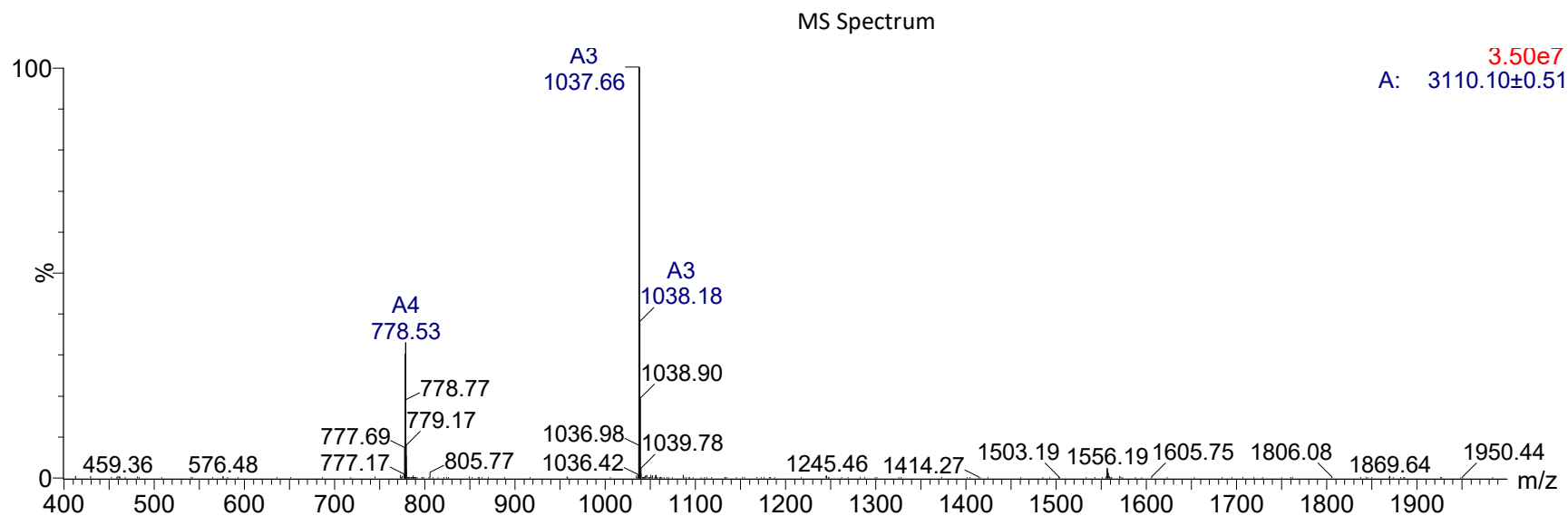
Sample Information

Product Name :Thymosin alpha 1
 Lot. No :20250815
 Sequence :Ac-Ser-Asp-Ala-Ala-Val-Asp-Thr-Ser-Ser-Glu-Ile-Thr-Thr-Lys-Asp-Leu-Lys-Glu-Lys-Lys-Glu-Val-Val-Glu-Glu-Ala-Glu-Asn
 Column : Kromasil, 100-3.5-C18,(4.6mm i.d.,250 mm L)
 Buffer : A: Ammonium sulfate buffer (take 26.4g ammonium sulfate, 25ml phosphoric acid, dissolve in water and dilute to 2000ml) - acetonitrile (90:10) B: Ammonium sulfate buffer - acetonitrile (50:50)
 Gradient :7-25% in 45 min
 Flow rate :0.8ml/min
 Wavelength :210nm
 Dissolution method :100%H₂O
 Column temperature 50°C



RT	Area	% Area	Height
1 24.857	2707	0.03	201
2 28.780	33331	0.42	1957
3 29.342	7779562	98.06	454310
4 29.827	51933	0.65	3907

RT	Area	% Area	Height
5 30.722	62556	0.79	1955
6 32.507	3055	0.04	203



3.50e7
A: 3110.10±0.51

Dissolution	:0.1%HCOOH+ACN	Interface	:ESI	Prerod Bias	:+3.5kv
Date	:2025/08/15 20:09:40	Nebulizing Gas Flow	:500L/hr	Detector	:-0.2kv
Injection	:2.5ul	CDL Temp	:400C	T.Flow	:0.35ml/min
Block Temp	:150	CDL Volt	:+35V	B.conc	:50%H2O/50%MEOH

Catalog ID :
Product Name : Thymosin alpha 1
Sequence : Ac-Ser-Asp-Ala-Ala-Val-Asp-Thr-Ser-Ser-Glu-Ile-Thr-Thr-Lys-Asp-Leu-Lys-Glu-Lys-Lys-Glu-Val-Val-Glu-Glu-Ala-Glu-Asn
Lot.No : 20250815
Theoretical : 3108.30
Observed : 3109.59