

## Pen peptide certificate of analysis (CoA)

<b>Product:</b>	<b>TB4</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> 25AUG	13TB4	
<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 7.4; 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.

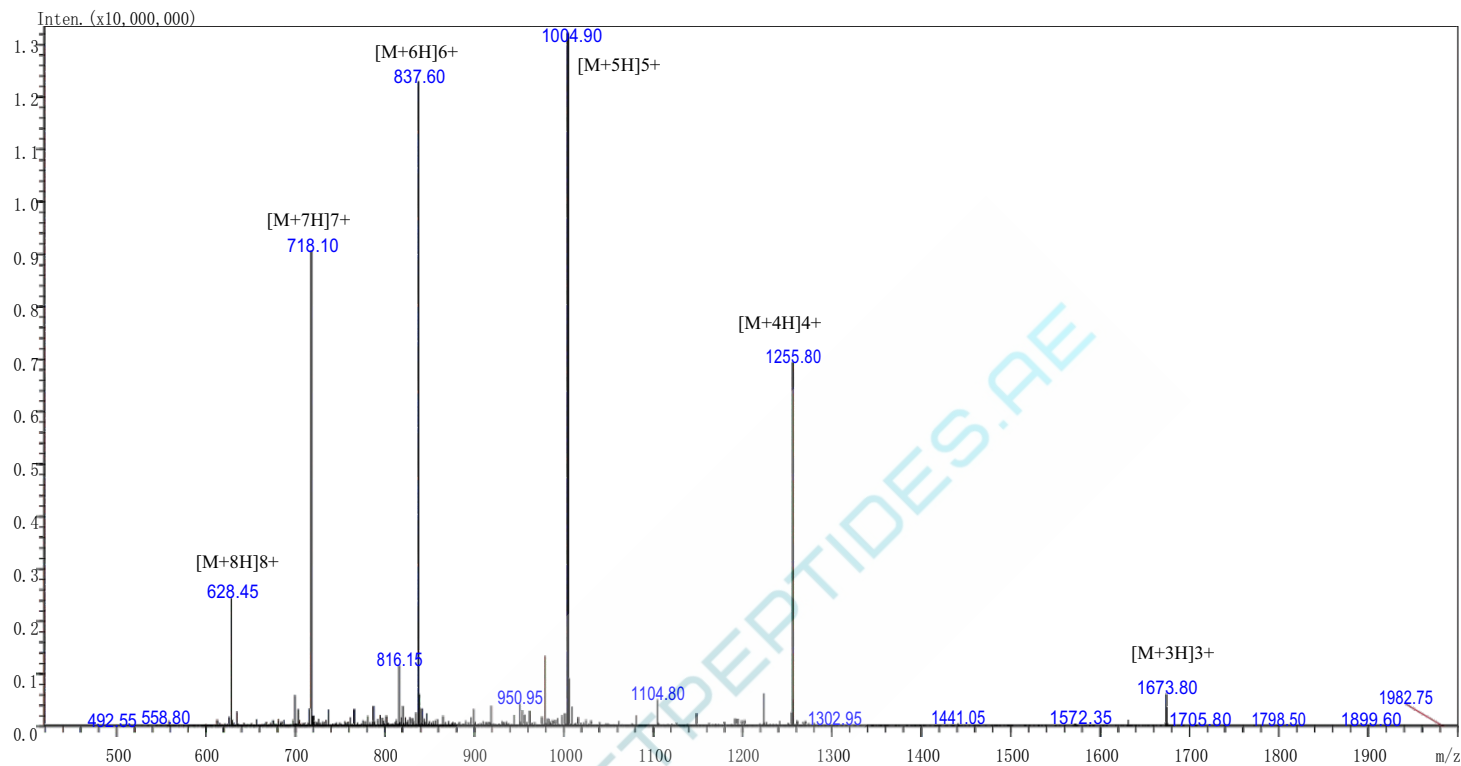
**Storage and stability:** Store material at +2 - +8°C. **Do not freeze!**

### **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.

MS Spectrum

Positive



Acquired by :PY  
Data Acquired : 2025/08/13  
Injection Volume : 1  
Sample Name : Thymosin beta 4  
Mw : 5020.50  
Lot No. : 20250813

Probe :ESI  
Nebulizer Gas Flow :1.5L/min  
CDL : -20.0v  
CDL Temp °C :250  
Block Temp °C :400  
Probe bias :+4.5kv  
Detector :1.2kv  
T.Flow :0.2ml/min  
B.conc :50%H2O/50%ACN

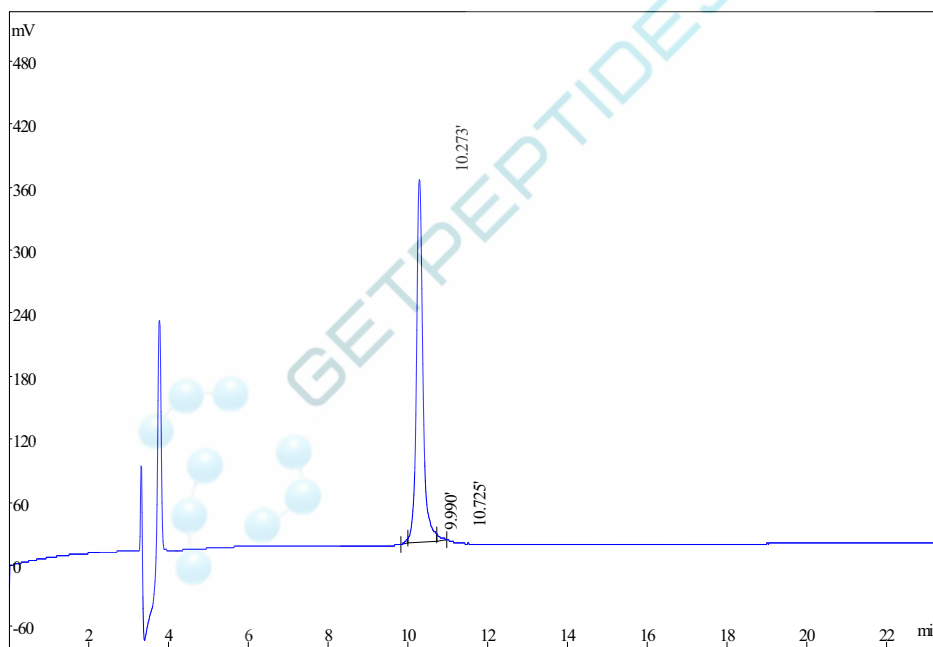


Structure : Thymosin beta 4  
 Lot NO : 20250813  
 Number :0200049  
 Column :250\*4.6mm,ChromCore 120-C18-5um  
 Solvent A:0.1%TFA in 100%water  
 Solvent B:0.1%TFA in 100%acetonitrile

Gradient :

	A	B
0.1min	83%	17%
25.0min	58%	42%
25.1min	0%	100%
30.0min	stop	

Flow rate:1.0ml/min  
 Wavelength(nm):220  
 Volume :10ul



Rank	Time	Conc.	Area	Height
1	9.990	0.5621	21158	4923
2	10.273	98.52	3708532	345056
3	10.725	0.9153	34451	5463
Total		100	3764141	355442