

Pen peptide certificate of analysis (CoA)

Product:	TB4
Source:	Hybrid synthesis (recombinant using peptide secretion system and chemical synthesis)
Intended use:	For stability, viability and activity testing only.
Order number:	Lot: 25AUG13TB4
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 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.

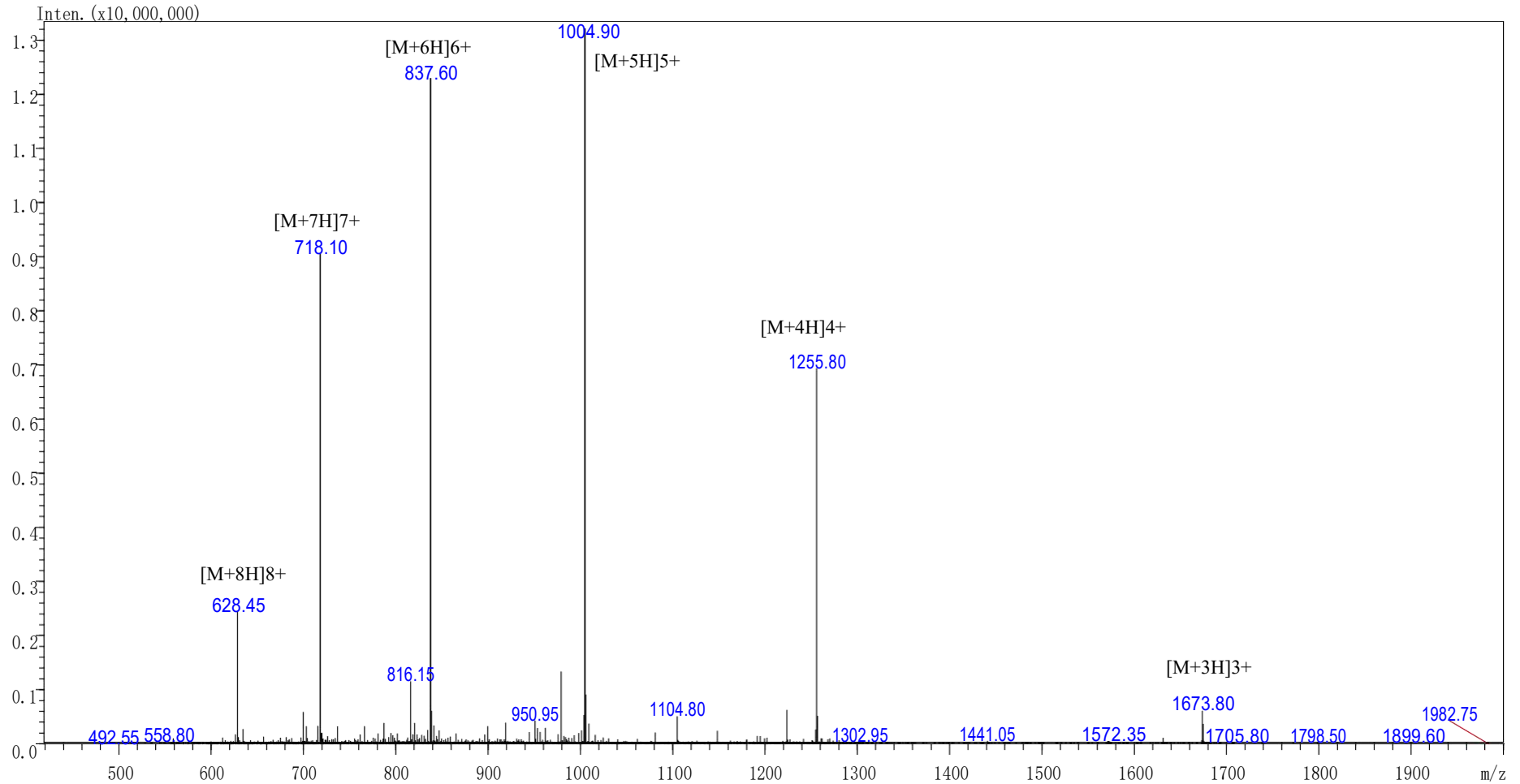
Storage and stability: Store material at +2 - +8°C. **Do not freeze!**

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



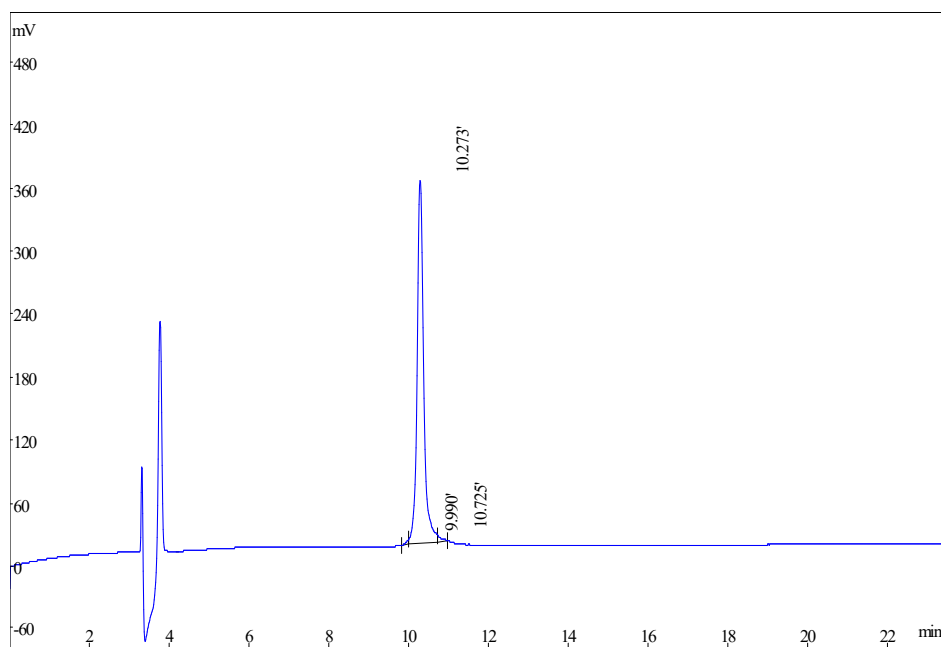
Acquired by :PY
Data Acquired : 2025/08/13
Injection Volume : 1
Sample Name : Thymosin beta 4
Mw : 5020.50
Lot No. : 20250813

Probe :ESI
Nebulizer Gas Flow :1.5L/min
CDL :-20.0v
CDL Temp :250°C
Block Temp :400°C
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