中析研究所
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Zhongxi Research Institute
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https://www.yjsba.com/jcxm/qita/16188.html
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CERTIFICATE OF ANALYSIS

Issued by an ISO/IEC 17025-accredited laboratory · raw data appended (page 2)

PASS
QC released for dispatch

Scan to verify

TB-500 — 10mg

Thymosin Beta-4

1. PRODUCT IDENTIFICATION

Synonym	Thymosin Beta-4	**Label claim**	10mg
Sequence / structure	Ac-SDKPDMAEIEKFDKSKLKKTETQEKNPLPSK ETIEQEKQAGES	**Lot / Batch**	ZX260512-449 / B42640
Mol. formula	C212H350N56O78S	**Manufacture date**	17 May 2026
Mol. weight	4963.44 g/mol	**Date of analysis**	23 May 2026
CAS number	77591-33-4	**Storage**	−20 °C, dark, desiccated
Salt form	Acetate salt		

2. ANALYTICAL TEST RESULTS

Test	Method	Specification	Result	Verdict
Appearance	Visual	White/off-white powder	White to off-white lyophilized powder	**PASS**
Identity (ESI-MS)	LC-MS	Matches 4963.44 Da	4963.49 Da (Δ 10 ppm)	**PASS**
Purity	RP-HPLC, UV 220 nm	≥ 98.0% area	98.93%	**PASS**
Related substances	RP-HPLC	Single ≤1.0 / Total ≤2.0%	0.72 / 1.07%	**PASS**
Water content	Karl Fischer (USP <921>)	≤ 8.0%	1.6%	**PASS**
Counter-ion: acetate	Ion chromatography	Report (3.0–15.0%)	10.3%	**PASS**
Net peptide content	Amino-acid analysis	≥ 80.0%	86.3%	**PASS**
Bacterial endotoxin	LAL kinetic (USP <85>)	< 5.0 EU/mg	0.07 EU/mg	**PASS**
Heavy metals	ICP-MS (ICH Q3D)	Conforms	Conforms	**PASS**

CONCLUSION
All tested parameters CONFORM to the acceptance specifications. The batch is of high chromatographic purity (≥ 98%) with an impurity profile, identity and residual/contaminant results meeting pharmaceutical-grade quality requirements. Material released. Supporting RP-HPLC chromatogram and ESI-MS spectrum are appended on page 2.

DLW.

Dr. Li Wenhua
Analyst · 23 May 2026 · Zhongxi Research Institute

DLX.

Dr. Lin Xia (QC Manager)
Approved by · 23 May 2026 · Zhongxi Research Institute

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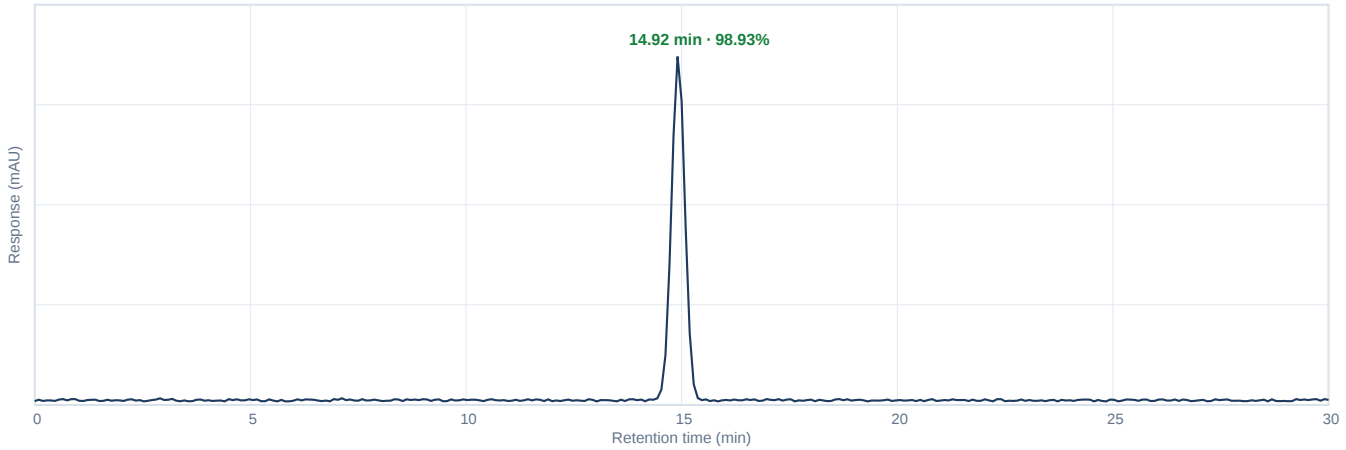
APPENDIX — ANALYTICAL RAW DATA

TB-500 10mg · Lot ZX260512-449 · Cert. ZXR-COA-2026-52066

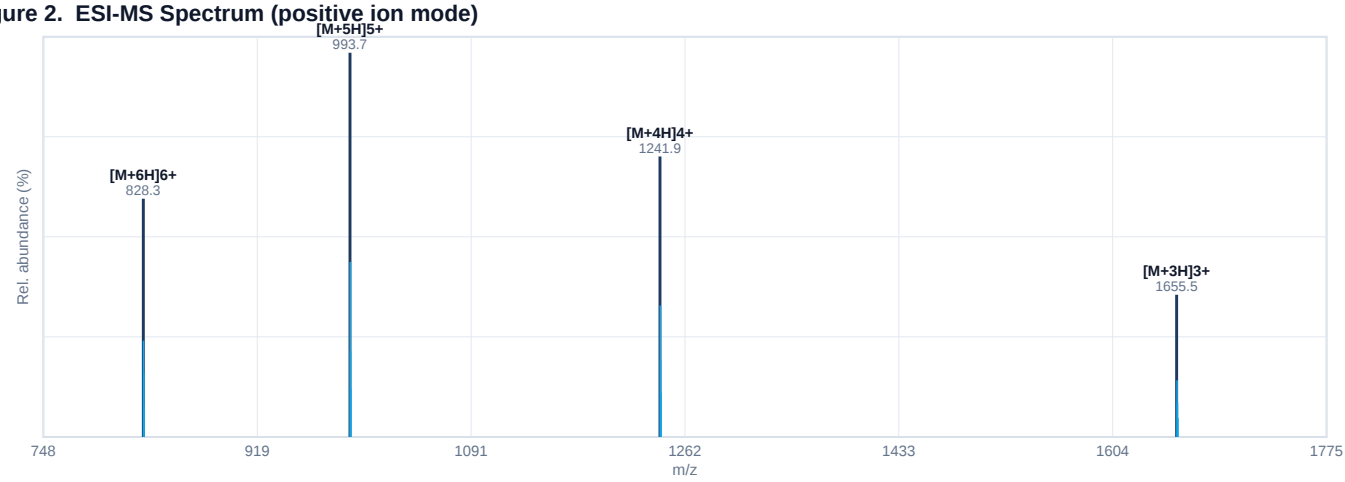
Scan to verify

Figure 1. RP-HPLC Chromatogram (UV 220 nm)



Peak #	RT (min)	Area (µV·s)	Area %	Assignment
1	14.92	1023881	98.93	Main (target)
2	3.01	3917	0.37	Impurity / related substance
3	7.13	3801	0.35	Impurity / related substance
4	17.11	2387	0.22	Impurity / related substance
5	7.94	1219	0.13	Impurity / related substance

Figure 2. ESI-MS Spectrum (positive ion mode)



Interpretation

Identity confirmed by ESI-MS. Observed ions [M+3H]3+ 1655.5, [M+4H]4+ 1241.9, [M+5H]5+ 993.7, [M+6H]6+ 828.3 deconvolute to a neutral monoisotopic-average mass of 4963.49 Da (theoretical 4963.44 Da; mass error 10 ppm), consistent with TB-500. No co-eluting species above 0.5% indicative of misidentification.

Methods — RP-HPLC: Agilent 1260 Infinity II; Zorbax SB-C18 4.6×250 mm, 5 µm; A: 0.1% TFA in water, B: 0.1% TFA in MeCN; 10–70% B over 30 min; 1.0 mL/min; 25 °C; 20 µL injection. MS: AB Sciex TripleTOF, ESI+, capillary 4.5 kV, deconvolution by Bio Tool Kit. KF: Metrohm 901. IC: Thermo Dionex ICS-6000. ICP-MS: Agilent 7900.