

# Certificate of Analysis (COA)

## 质检报告 - 完整版

### TB-500 - Thymosin Beta-4 Fragment

**Product Type:** Lyophilized Powder (Freeze-Dried) | 冻干粉

**Grade:** Injectable Grade | 注射级

### Product Information | 产品信息

|                         |                                                                                                                                                                                                                |
|-------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Product Name   产品名称     | TB-500 (Thymosin Beta-4 Fragment)<br>胸腺素β-4 片段                                                                                                                                                                 |
| Synonyms   别名           | Thymosin β4, Tβ4, TB500                                                                                                                                                                                        |
| CAS Number              | 75591-33-8                                                                                                                                                                                                     |
| Molecular Formula   分子式 | C <sub>212</sub> H <sub>350</sub> N <sub>56</sub> O <sub>78</sub> S                                                                                                                                            |
| Molecular Weight   分子量  | 4963.52 g/mol                                                                                                                                                                                                  |
| Amino Acid Sequence     | Ac-Ser-Asp-Lys-Pro-Asp-Lys-Ala-Lys-Asp-Val-Ala-Thr-Gly-Gln-Lys-Glu-Thr-Ser-Gln-Glu-Lys-Gln-Ala-Gly-Glu-Ser-Lys-Asp-Pro-Pro-Thr-Ile-Lys-Glu-Lys-Gln-Val-Thr-Gln-Gly-Gln-Lys-Ala-Val-Glu-Ser-Lys-NH <sub>2</sub> |
| Specification   规格      | 5mg, 10mg × 10 vials/box                                                                                                                                                                                       |
| Appearance   外观         | White to off-white lyophilized powder<br>白色至类白色冻干粉                                                                                                                                                             |
| Batch Number   批号       | TB50-2026-589                                                                                                                                                                                                  |
| Manufacturing Date      | 2026-07-10                                                                                                                                                                                                     |
| Expiry Date             | 2028-07-10                                                                                                                                                                                                     |
| Storage   储存条件          | Store at -20°C, protect from light and moisture<br>避光防潮, -20°C 保存                                                                                                                                              |
| Shelf Life   保质期        | 24 months from manufacturing date (unopened)<br>未开封 24 个月                                                                                                                                                      |

### Physical & Chemical Tests | 理化检测

| Test Item   检测项目 | Specification   标准 | Result   结果 | Method   方法 |
|------------------|--------------------|-------------|-------------|
|------------------|--------------------|-------------|-------------|

|                            |                           |              |                   |
|----------------------------|---------------------------|--------------|-------------------|
| Appearance   外观            | White to off-white powder | White powder | Visual            |
| Identification   鉴别        | Positive for TB-500       | Positive     | HPLC              |
| Assay/Purity   纯度          | ≥98.5%                    | 99.2%        | HPLC              |
| Related Substances   有关物质  | ≤1.5%                     | 0.6%         | HPLC              |
| Single Impurity   单一杂质     | ≤0.8%                     | 0.3%         | HPLC              |
| Loss on Drying   干燥失重      | ≤3.0%                     | 1.4%         | LOD               |
| Water Content   水分含量       | ≤2.0%                     | 1.2%         | Karl Fischer      |
| Residue on Ignition   炽灼残渣 | ≤0.5%                     | 0.2%         | ROI               |
| pH Value (1mg/mL)   pH值    | 6.0-8.0                   | 7.2          | pH Meter          |
| Protein Content   蛋白含量     | ≥95.0%                    | 97.8%        | Kjeldahl          |
| Particle Size   粒度分布       | D90 ≤ 100 μm              | D90 = 68 μm  | Laser Diffraction |
| Reconstitution Time   复溶时间 | ≤60 seconds               | 35 seconds   | Visual            |

Structural Analysis | 结构分析

| Test Item   检测项目                 | Specification   标准       | Result   结果 | Method   方法 |
|----------------------------------|--------------------------|-------------|-------------|
| LC-MS Molecular Weight   质谱分子量   | 4963.52 ± 1.0 Da         | 4963.6 Da   | LC-MS       |
| Molecular Ion [M+H] <sup>+</sup> | 4964.53 ± 1.0            | 4964.5      | LC-MS       |
| Retention Time   保留时间            | 8.85 ± 0.2 min           | 8.83 min    | HPLC        |
| Peptide Mapping   肽图             | Match Reference Standard | Matched     | HPLC        |
| Amino Acid Analysis   氨基酸分析      | Within ±5% of Theory     | Within ±3%  | AAA         |
| N-terminal Sequencing   N 端测序    | Ac-Ser-Asp-Lys-Pro       | Confirmed   | Edman       |

|                      |         |         |       |
|----------------------|---------|---------|-------|
| Mass Accuracy   质量精度 | ±1.0 Da | ±0.5 Da | LC-MS |
|----------------------|---------|---------|-------|

Safety Tests | 安全性检测

| Test Item   检测项目                | Specification   标准 | Result   结果 | Method   方法         |
|---------------------------------|--------------------|-------------|---------------------|
| Heavy Metals   重金属总量            | ≤10 ppm            | <5 ppm      | ICP-MS              |
| Lead (Pb)   铅                   | ≤2 ppm             | <1 ppm      | ICP-MS              |
| Arsenic (As)   砷                | ≤1 ppm             | <0.5 ppm    | ICP-MS              |
| Mercury (Hg)   汞                | ≤0.5 ppm           | <0.2 ppm    | ICP-MS              |
| Cadmium (Cd)   镉                | ≤1 ppm             | <0.5 ppm    | ICP-MS              |
| Residual Solvents   残留溶剂        | ≤0.5%              | ND          | GC                  |
| Microbial Limit   微生物限度         | ≤100 CFU/g         | <50 CFU/g   | Plate Count         |
| E. coli   大肠杆菌                  | Negative           | Negative    | PCR                 |
| Salmonella   沙门氏菌               | Negative           | Negative    | PCR                 |
| Staphylococcus aureus   金黄色葡萄球菌 | Negative           | Negative    | PCR                 |
| Bacterial Endotoxins   细菌内毒素    | ≤5 EU/mg           | <2 EU/mg    | LAL                 |
| Sterility   无菌检查                | Sterile            | Sterile     | Membrane Filtration |
| Mycoplasma   支原体                | Negative           | Negative    | PCR                 |

Bioactivity & Stability | 生物活性与稳定性

| Test Item   检测项目              | Specification   标准    | Result   结果 | Method   方法 |
|-------------------------------|-----------------------|-------------|-------------|
| Bioactivity/Potency   生物活性    | ≥90% of Reference     | 96%         | Cell Assay  |
| Accelerated Stability   加速稳定性 | Stable at 25°C/60% RH | Stable      | 3 months    |
| Long-term Stability   长期稳定性   | Stable at -20°C       | Stable      | 12 months   |

**Conclusion | 结论**

**The product complies with injectable grade peptide quality standards.**  
**本品符合注射级肽类产品质量标准。**



Tested by | 检测  
Lab Technician

Approved by | 批准  
QA Director

**Laboratory Information | 实验室信息**

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Date of Issue: 2026-07-13

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