

Technical Data Sheet (TDS)

1. Product Overview

- **Product Name:** Thymosin (胸腺素)
- **CAS Number:** N/A (Natural polypeptide mixture)
- **Formula:** Blend of Natural Thymic Polypeptides (Thymosin $\alpha 1$, $\beta 4$, Thymopentin, etc.)
- **Formula Weight:** Variable (3000-10000 Da)
- **Molecular Form:** Natural biological active polypeptide mixture (extracted from animal thymus)
- **Product Characteristics:** High-purity pharmaceutical/research grade Thymosin is a natural polypeptide mixture extracted and purified from mammalian thymus, with potent immunomodulatory activity. Off-white odorless lyophilized powder, soluble in water, stable under refrigerated storage. Regulates T-lymphocyte maturation and immune function, FDA/EMA approved for immunodeficiency disease treatment; low toxicity, high biocompatibility, widely used in pharmaceutical and immunology research fields.

2. Technical Specifications (CP/USP/EP Compliant)

Item	Specification (Pharmaceutical Grade)
Appearance	White to off-white lyophilized powder
Total Polypeptide Content	$\geq 85.0\%$ (Lowry Method)
Thymosin $\alpha 1$ Purity	$\geq 20.0\%$ (HPLC)
Loss on Drying (60°C, vacuum)	$\leq 3.0\%$
Residue on Ignition (600°C)	$\leq 0.5\%$
Heavy Metals (Pb)	≤ 5 ppm (AAS)
Heavy Metals (As)	≤ 1 ppm (AFS)
pH Value (1mg/mL aqueous, 25°C)	6.0-8.0
Water Content (Karl Fischer)	$\leq 3.0\%$
Bacterial Endotoxins	≤ 0.5 EU/ μ g (LAL Test)
Total Aerobic Count	≤ 50 CFU/g
Pathogens (E. coli/Staph. aureus)	Negative
Solubility	Soluble in water, dilute phosphate buffer
Particle Size	200-300 mesh
Hygroscopy	Slight (stable at RH $\leq 60\%$)
Storage Stability	24 months (2-8°C, unopened); 1 month (4°C, after opening)

3. Product Advantages

1. **Natural Immunomodulator:** Extracted from natural thymus tissue; high biocompatibility, low immunogenicity, mild and lasting immunomodulatory effect.
2. **Multi-component Synergy:** Contains multiple active thymic polypeptides ($\alpha 1$, $\beta 4$, etc.) with synergistic effects; broader immunoregulatory activity than single-component thymosin.
3. **High Purity & Quality:** $\geq 85\%$ total polypeptide content, strict heavy metal/microbial control; meets global pharmacopoeia (CP/USP/EP) standards; GMP compliant.
4. **Stable Physical Properties:** Lyophilized powder with slight hygroscopy; stable under refrigerated storage, easy for formulation, transportation and storage.
5. **Low Toxicity Profile:** No acute systemic toxicity; only mild eye/skin irritation; no chronic target organ toxicity at therapeutic dosages.
6. **Versatile Application:** Suitable for pharmaceutical, biomedical research and cell culture fields; compatible with various excipients and formulation processes.

4. Application Fields

- **Pharmaceutical Industry:** Production of immunomodulatory formulations (injection, oral preparation) for primary/secondary immunodeficiency diseases, tumor adjuvant therapy, infectious disease treatment.
- **Biomedical Research:** Research reagent for immunology, cell biology, virology; T-lymphocyte maturation and activation research; immune disorder model research.



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- **Cell Culture:** Cell culture supplement for immune cell culture (T cells, NK cells); promotes immune cell proliferation and activation in vitro.
- **Veterinary Medicine:** Livestock/poultry immunomodulator; improves animal immune function, reduces infectious disease incidence.

5. Usage Methods

- **Pharmaceutical Formulation (Injection):** Dissolve in sterile water for injection/physiological saline to prepare 0.5-1 mg/mL injectable solution; adjust pH to 6.5-7.0 with phosphate buffer; sterile filtration for clinical use.
- **Pharmaceutical Formulation (Oral):** Mix with excipients (mannitol, lactose) to prepare oral powder/tablet; add enteric coating to avoid gastric acid degradation.
- **Research Use:** 0.1-10 µg/mL concentration for in vitro cell experiments; 0.1-1 mg/kg body weight for in vivo animal experiments; dissolve in sterile phosphate-buffered saline (PBS) to prepare stock solution (store at 4°C for 1 month).
- **Cell Culture:** Add to culture medium at 0.01-0.1 µg/mL concentration; promotes T/NK cell proliferation and activation.
- **Critical Notes:**
 1. Raw powder for pharmaceutical use only under GMP conditions; no direct human/animal use (unformulated).
 2. Avoid use in thymosin/polypeptide-allergic individuals; discontinue use if allergic reaction occurs.
 3. Strict refrigerated storage; avoid high temperature/moisture to prevent polypeptide degradation.

6. Packaging & Storage

Packaging Specifications (Sealed/Refrigerated/Moisture-Proof)

- 10 mg/vial (pharmaceutical GMP grade, sealed glass vial with rubber stopper + aluminum crimp seal)
- 50 mg/vial (research grade, sealed glass vial)
- 1 g/bottle (bulk grade, HDPE plastic bottle with moisture-proof cap)
- 5 kg/drum (industrial/veterinary grade, HDPE plastic drum with inner aluminum foil bag)
- Custom packaging (1 mg/5 mg) for research/small-batch orders available on request.

Storage Conditions (Refrigerated Mandatory)

- **Long-term Storage:** 2-8°C (refrigerated), dry, dark, **sealed**; store in original packaging; avoid temperature fluctuation (>10°C).
- **Short-term Storage:** 4°C (refrigerated), up to 1 month after opening; keep sealed and dry (RH ≤60%).
- **Avoid:** High temperature (>40°C), direct sunlight, high humidity (RH >60%), strong acids/bases, proteolytic enzymes, heavy metal ions.
- **Segregation:** Store separately from food/feed, pharmaceuticals (other biologics), strong acids/bases; store in dedicated polypeptide refrigerated storage area (2-8°C).

7. Safety & Protection

- The product may cause **allergic skin reactions** in sensitive individuals and **serious eye irritation**; no acute systemic toxicity.
- **Mandatory PPE** for handling: chemical safety goggles, N95/P95 dust mask, powder-free nitrile gloves (≥0.18mm), disposable lab coat.
- Operate in well-ventilated area; avoid dust generation/inhalation and skin/eye contact; wash hands thoroughly after handling.

8. Quality Assurance

- Manufactured in accordance with **GMP (Good Manufacturing Practice)**, **ISO 9001 (Quality)** and **ISO 14001 (Environment)** standards.
- Each batch is tested by an independent third-party laboratory and accompanied by a **Certificate of Analysis (COA)** with full purity/activity test data.