

Technical Data Sheet (TDS)

1. Product Overview

- Product Name: Thyroxine
- English Name: Thyroxine (L-T4)
- CAS Number: 51-48-9
- Formula: $C_{15}H_{11}I_4NO_4$
- Molecular Weight: 776.87 g/mol
- Product Characteristics: High-purity L-thyroxine, white odorless crystalline powder, biopharmaceutical grade. Soluble in alkaline solutions and polar organic solvents, insoluble in water. Ultra-high HPLC purity ($\geq 98.5\%$) and assay ($\geq 98.0\%$), low moisture/heavy metal content. Stable at 2-8°C for 24 months, degrades at high temperature/strong oxidizing conditions. Mild irritant to skin/eyes; prolonged exposure may affect thyroid function. Suitable for biopharmaceutical R&D and endocrinology research.

2. Technical Specifications (Biopharmaceutical Grade)

Item	Specification
Appearance	White to off-white crystalline powder
Purity (HPLC)	$\geq 98.5\%$
Assay (Titration)	$\geq 98.0\%$
Melting Point	230-235°C (decomposition)
Moisture Content	$\leq 0.5\%$
Heavy Metals (Pb)	≤ 5 ppm
Heavy Metals (As)	≤ 1 ppm
Optical Rotation ($[\alpha]_{20}^D$, 0.1M NaOH)	+18 to +22°
Solubility	Soluble in 0.1M NaOH/DMSO; slightly soluble in methanol
Residue on Ignition	$\leq 0.1\%$
Storage Stability	24 months (2-8°C, sealed, protected from light)
Opened Stability	6 months (2-8°C, tightly sealed)

3. Product Advantages

1. Ultra-High Purity: $\geq 98.5\%$ HPLC purity and $\geq 98.0\%$ assay, ultra-low impurities (moisture/heavy metals/residue); consistent batch-to-batch quality for reliable thyroid research results.
2. Excellent Stability: 24-month shelf life at 2-8°C; anhydrous pure form with no excipients ensures long-term chemical stability for long-term R&D projects.
3. USP/EP Compliant: Manufactured to meet United States Pharmacopeia and European Pharmacopoeia standards; suitable for biopharmaceutical drug development and in vitro diagnostics.
4. Well-Characterized: Exact optical rotation, melting point and solubility profile; full physicochemical and analytical data provided for experimental design and validation.
5. Versatile Solubilization: Soluble in common alkaline buffers (0.1M NaOH) and polar organic solvents (DMSO/methanol); compatible with most biological buffers for experimental use.
6. Quality Assured: Manufactured under ISO 9001 quality management system; strict quality control at every production step; each batch with a comprehensive Certificate of Analysis.

4. Application Fields

- Biopharmaceutical R&D: Thyroxine drug development, formulation research, potency testing and quality control of levothyroxine medications for thyroid disorder treatment.
- In Vitro Diagnostics: Raw material for T4 immunoassay kits (ELISA, chemiluminescence, RIA); clinical diagnostic reagent for thyroid function detection (hypothyroidism, hyperthyroidism, thyroiditis).
- Endocrinology Research: Thyroid hormone synthesis/metabolism study, hypothalamic-pituitary-thyroid (HPT) axis research, endocrine disorder mechanism and treatment experiment.
- Cellular/Molecular Research: T4 receptor binding assay, thyroid hormone-mediated signal transduction research, endocrine cell culture and model construction.



NEWAY SINOPHC TECH. LIMITED

ADD:RM. 204, BUILDING 3, NO. 188, AONA RD., CHINA (SHANGHAI) PILOT FREE TRADE ZONE.
Email:marketing01@newayphc.com; Phone:+86-021-50350029 <https://www.newayphc.com>

- Academic Research: Peptide hormone structure-activity relationship study, thyroid hormone bioavailability research, endocrine toxicology and environmental endocrine disruptor experiment.

5. Usage Methods

- Solubilization: Prepare a 5 mM stock solution by dissolving in 0.1M NaOH or DMSO (mix gently until fully dissolved); avoid direct addition to water (insoluble). For aqueous solutions, dilute alkaline/DMSO stock with deionized water/PBS (pH 7.4) to the desired concentration.
- Stock Solution Storage: 5 mM stock solution stored at 2-8°C for ≤3 months (sealed, dark); aliquot and freeze at -20°C for long-term use (avoid repeated freeze-thaw cycles); use amber glass vials for all storage to protect from light.
- Working Concentration: Dilute stock solution with cell culture medium/PBS to working concentration (0.1-50 nM for cellular experiments; 0.1-5 µg/mL for in vitro immunoassays; adjust according to research design and model).
- Optimal Conditions: Use sterile technique for cell culture and diagnostic reagent applications; perform in vitro experiments at 25±2°C and cell culture at 37°C/5% CO₂; protect all solutions from light/oxidizing conditions; discard unused stock solution after 3 months of preparation.

6. Packaging & Storage

- Packaging Specifications: 1g/bottle, 5g/bottle, 10g/bottle, 50g/bottle (amber glass bottles with Teflon-lined screw caps); customized packaging (100g-1kg) available for large-scale R&D projects upon request.
- Storage Conditions: **2-8°C (refrigerated)**, dark, hermetically sealed; store in amber glass packaging to prevent light degradation; avoid exposure to moisture, heat and strong oxidizing agents; store in a dedicated chemical refrigerator (separated from food, biological reagents and strong acids/oxidizers).
- Shelf Life: 24 months for unopened products under 2-8°C sealed, light-proof storage conditions; 6 months for opened products (2-8°C, tightly resealed); 12 months for aliquoted stock solutions stored at -20°C (dark, sealed).
- Transportation: Classified as UN 3077 Class 9 environmentally hazardous substance; **2-8°C refrigerated transport** with insulated, light-proof packaging and ice packs; comply with IMDG/IATA/ADR international transport regulations; avoid direct sunlight, high temperature and violent collision during transportation.

7. Safety & Protection

- Mandatory PPE: Wear nitrile chemical gloves, chemical splash goggles, N95 dust mask and lab coat for all handling operations; use a fume hood for bulk weighing, solubilization and large-scale processing.
- Handling Precautions: Strictly avoid skin/eye contact and dust inhalation; use light-proof glassware and amber vials for all solution preparation and storage; wash hands and exposed skin thoroughly with soap and water after handling; no eating, drinking or smoking in the laboratory work area.

8. Quality Assurance

- Manufactured in strict accordance with ISO 9001 international quality management system; implement strict raw material inspection, high-purity synthesis process control and multi-step purification (recrystallization + preparative HPLC).
- Each batch undergoes comprehensive quality testing including purity, assay, physicochemical properties, heavy metals and impurities; every batch is accompanied by a detailed Certificate of Analysis (COA) complying with USP/EP biopharmaceutical standards.
- All raw materials and production auxiliary materials are sourced from ISO/GMP-certified suppliers; full traceability of production, testing, packaging and shipping processes for all batches to ensure quality accountability.