

## Technical Data Sheet (TDS)

**Duloxetine Hydrochloride CAS:136434-34-9 Version Date: 28 FEB 2026**

### 1. Product Overview

- Product Name: Duloxetine Hydrochloride (盐酸度洛西汀)
- CAS Number: 136434-34-9
- Formula: C<sub>18</sub>H<sub>19</sub>NOS·HCl
- Molecular Weight: 333.88 g/mol
- Chemical Classification: Serotonin-Norepinephrine Reuptake Inhibitor (SNRI)
- Product Grade: Pharmaceutical Grade (EP/USP/CP Compliant)
- Product Characteristics: High-purity chiral crystalline powder; potent dual-acting antidepressant/anticonvulsant API; soluble in water and organic solvents; light-sensitive; stable under controlled storage conditions; high batch-to-batch consistency

### 2. Technical Specifications (EP 10.0 / USP 45 / CP 2020)

Item	Specification	Test Method
Appearance	White to off-white crystalline powder	Visual Inspection
Assay (on dry basis)	≥ 98.5%	HPLC
Melting Point	176-182°C	Capillary Melting Point Method
Loss on Drying	≤ 0.5%	105°C Gravimetry (2h)
Residue on Ignition	≤ 0.1%	550°C Ignition Method
Heavy Metals (Pb)	≤ 10 ppm	AAS
Heavy Metals (As)	≤ 2 ppm	AFS
Related Substances	Each impurity ≤ 0.5%; Total ≤ 1.0%	HPLC
Chloride Content	10.5-11.5% (dry basis)	Volumetric Titration
Optical Rotation	+101.0° to +107.0° (1% in methanol)	Polarimetry
pH Value (1% aq. solution)	4.5-6.5	Digital pH Meter
Solubility	Soluble in water, methanol	Pharmacopoeial Solubility Test
Particle Size	90% passing 100 mesh	Sieve Analysis
Specific Rotation	+103° ± 2° (1% in methanol)	Polarimetry

### 3. Product Advantages

1. **Dual Pharmacological Activity:** Serotonin-norepinephrine reuptake inhibitor (SNRI); effective for major depressive disorder, generalized anxiety disorder and diabetic peripheral neuropathic pain; broader therapeutic profile than single-acting SSRIs.
2. **International Compliance:** Meets EP/USP/CP pharmacopoeial standards; low related substances and heavy metal content; suitable for GMP pharmaceutical formulation.
3. **Chiral Purity:** High optical purity (+101.0° to +107.0°); no racemic impurities; consistent pharmacological activity across batches.
4. **Formulation Flexibility:** Soluble in water and organic solvents; suitable for solid oral dosage forms (tablets, capsules) and oral liquid formulations.
5. **GMP Quality:** Produced in a GMP/ISO 9001 certified facility; complete raw material traceability; strict in-process and finished product quality control.

### 4. Application Fields

- **Pharmaceutical Formulation:** Production of antidepressant/antianxiety drugs (delayed-release tablets, capsules, oral solutions) for major depressive disorder, generalized anxiety disorder, fibromyalgia and diabetic peripheral neuropathic pain.



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- **Pharmaceutical R&D:** Research on new SNRI formulations (extended-release, topical); preclinical/clinical research on chronic pain and mood disorders; drug-drug interaction studies.
  - **Academic Research:** Neuroscience research on serotonin/norepinephrine receptor pharmacology; chronic pain pathway research; antidepressant drug development.
- ### 5. Usage & Formulation Guidelines
- **Formulation Compatibility:** Suitable for delayed-release/sustained-release solid oral dosage forms (primary application) and oral liquid formulations; no special solubilizers required for aqueous preparations.
  - **Typical Dosage (Formulated Drug):** Adult oral dosage 60-120 mg/day (as duloxetine hydrochloride) – **dosage subject to pharmaceutical formulation and clinical prescription.**
  - **Processing Precautions:** Process in a **light-free, dust-free, GMP-compliant** workshop; maintain low humidity (<60%); use closed handling systems to prevent dust generation and light exposure; avoid contact with strong acids/bases/oxidizing agents.
- ### 6. Packaging & Storage
- #### 6.1 Packaging Specifications
- 100 g/bottle (amber glass bottle with aluminum foil seal, inner plastic liner – light-resistant)
  - 500 g/bottle (amber glass bottle with aluminum foil seal)
  - 1 kg/drum (opaque HDPE drum with inner plastic bag, sealed)
  - 5 kg/drum (fiber drum with opaque HDPE inner liner, sealed)
  - Custom light-resistant GMP packaging available for industrial bulk orders
- #### 6.2 Storage Conditions
- Store in a cool, dry, dark warehouse at **15-25°C**; use light-resistant packaging; keep container tightly sealed to prevent moisture and light exposure.
  - Protect from direct sunlight, high temperature (>30°C) and high humidity (>60%); do not freeze.
  - Store separately from strong acids, strong bases, oxidizing agents, food and feed materials.
  - Shelf Life: **24 months** (unopened, specified conditions); 3 months after opening (resealed, 15-25°C, dark).
- #### 6.3 Transportation
- Classified as UN 2811 (Class 6.1 Toxic Substance); transport with temperature-controlled packaging (maintain 15-25°C) and light protection.
  - Use opaque, sealed, chemical-resistant packaging; mark with GHS hazard labels, UN number, "Keep in Dark" and "15-25°C Storage" instructions.
  - Avoid collision, vibration, direct sunlight and temperature fluctuation during transport; comply with IMDG/IATA/ADR for Class 6.1 goods.
- ### 7. Quality Assurance
- Manufactured in a **GMP and ISO 9001 certified** production facility; strict in-process and finished product quality control for all parameters.
  - Each batch is tested for full quality characteristics; a batch-specific Certificate of Analysis (COA) is provided with every shipment.
  - Complete raw material and production traceability; quality records retained for 5 years (per GMP regulatory requirements).
  - Professional technical support provided for formulation development, processing optimization, stability testing and regulatory compliance.