

Technical Data Sheet (TDS)

1. Product Overview

- Product Name: Tapentadol Hydrochloride
- English Name: Tapentadol Hydrochloride
- CAS Number: 143562-04-5
- Formula: C₁₄H₂₁NO·HCl
- Molecular Weight: 255.78 g/mol
- Product Characteristics: High-purity chiral pharmaceutical grade Tapentadol Hydrochloride is a white crystalline powder, a novel central analgesic drug raw material with dual action of opioid receptor agonism and norepinephrine reuptake inhibition. It has high optical purity ($[\alpha]_{20}^D$ +7.0°~+9.0°), good water solubility, stable quality, and meets USP 45 standards. It is suitable for the production of oral solid preparations (tablets, capsules) and oral solutions, with strong and long-acting analgesic effects for moderate to severe acute pain.

2. Technical Specifications (Complies with USP 45 Pharmaceutical Standards)

Item	Specification
Appearance	White to off-white crystalline powder
Assay (HPLC)	≥ 99.5%
Melting Point	200-204°C
Loss on Drying	≤ 0.5%
Residue on Ignition	≤ 0.1%
Heavy Metals (Pb)	≤ 5 ppm
Related Substances (Individual)	≤ 0.05%
Related Substances (Total)	≤ 0.3%
Optical Rotation ($[\alpha]_{20}^D$)	+7.0° to +9.0° (5% in water)
pH Value (5% aqueous solution, 25°C)	4.0-6.0
Solubility	Freely soluble in water; soluble in ethanol; slightly soluble in acetone
Particle Size	95% passing 120 mesh
Microbial Limit	Total Aerobic Microbial Count ≤50 CFU/g; Yeast & Mold ≤5 CFU/g; Pathogens Negative

3. Product Advantages

1. **Ultra-High Purity & Chiral Purity:** Pharmaceutical grade with assay ≥99.5%, low related substances, high optical purity, meeting the strictest USP 45 standards.
2. **Excellent Water Solubility:** Freely soluble in water, no need for solubilizer, suitable for various oral formulation development and preparation of liquid preparations.
3. **Long Shelf Life:** 36-month shelf life under 2-8°C refrigerated storage, stable chemical properties, no easy degradation.
4. **Good Processability:** Uniform particle size, good flowability and compressibility, suitable for direct compression and wet granulation, high production efficiency.
5. **Complete Technical Documents:** With COA, MSDS, DMF and other complete documents, meeting the import/export and production approval requirements of various countries.

4. Application Fields

- **Pharmaceutical Production:** Core raw material for central analgesic drugs, used to produce Tapentadol Hydrochloride immediate-release tablets, extended-release tablets and oral solutions, for the treatment of moderate to severe acute pain (e.g., postoperative pain, cancer pain, musculoskeletal pain).
- **R&D Application:** Used in pharmaceutical research and development, pain pharmacology experiments, preclinical and clinical trial samples for new analgesic drugs.



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- **Other Fields:** Strictly limited to pharmaceutical manufacturing; no non-pharmaceutical use is allowed.
- **5. Usage Methods**
- **Formulation Compatibility:** Highly compatible with common pharmaceutical excipients (mannitol, lactose, microcrystalline cellulose, magnesium stearate, crospovidone, hydroxypropyl methylcellulose).
- **Processing Conditions:** Process at 15-25°C, relative humidity ≤50%; refrigerate raw material during production to avoid high temperature (>25°C); avoid contact with strong acid/alkali/oxidizing agents.
- **Dosage in Formulation:** Adjust according to drug specifications (common specifications: 50mg, 75mg, 100mg per immediate-release tablet; 100mg, 200mg per extended-release tablet).
- **Mixing Requirement:** Mix evenly with excipients (mixing time ≥20 minutes) to ensure content uniformity (RSD ≤1%).
- **6. Packaging & Storage**
- **Packaging Specifications:**
 - 1 kg/bag (aluminum foil vacuum bag, insulated HDPE drum outer packing)
 - 5 kg/drum (insulated HDPE drum with aluminum foil inner lining, sealed)
 - 10 kg/drum (insulated HDPE drum with aluminum foil inner lining, sealed)
 - Custom small packaging (100g/500g) available for R&D use.
- **Storage Conditions:** Store in a locked, cool, dark, well-ventilated warehouse at **2-8°C** (mandatory refrigeration); keep container tightly closed; avoid direct sunlight/moisture/strong acid/alkali; relative humidity ≤50%.
- **Shelf Life:** 36 months (unopened, under specified refrigerated storage conditions); 3 months after opening (seal tightly and continue refrigeration).
- **Transportation:** Class 9 hazardous goods; transport with temperature-controlled insulated vehicles (2-8°C); mark with "Refrigerated Cargo" and "Hazardous Goods"; avoid direct sunlight, high temperature, collision and rain during transport.
- **7. Safety & Protection**
- The product is a controlled pharmaceutical raw material, **strictly prohibited for direct human/animal consumption and non-pharmaceutical use**; store in a locked warehouse and manage with a special person.
- Wear full PPE (chemical splash goggles, nitrile rubber gloves, impermeable lab coat, N95 dust mask) during all handling operations; avoid inhaling dust and direct contact with eyes/skin.
- Operate in a well-ventilated fume hood; do not eat, drink or smoke in the handling area; wash hands/face thoroughly after operation.
- In case of eye contact, rinse with plenty of water for 10-15 minutes and consult a doctor immediately; if accidentally swallowed, call a poison center/doctor immediately and do not induce vomiting.
- Non-combustible, no fire/explosion risk; store away from strong acid/alkali/oxidizing agents.
- **8. Quality Assurance**
- 1. Produced in accordance with GMP, ISO 9001 quality management system and ISO 14001 environmental management system standards.
- 2. Each batch of product is strictly tested and accompanied by a detailed Certificate of Analysis (COA) to ensure all indicators meet USP 45 standards.
- 3. Provide complete technical documents including MSDS, TDS, DMF and quality inspection reports to meet customer's production and approval needs.
- 4. Accept third-party inspection (SGS, Intertek, FDA, CNAS) for product purity, chiral purity and impurity content.
- 5. Provide professional technical support: formulation development, production process optimization, dissolution testing and quality control guidance, 24/7 technical consultation.