纳维盈医化科技
NEWAY SINOPHC TECH

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

Technical Data Sheet (TDS)

Issue Date: 29 FEB 2026Version: V1.0

1. Product Overview

- **Product Name**: Dexmedetomidine Hydrochloride
- **CAS Number**: 153006-60-5
- **Molecular Formula**: $C_{13}H_{16}N_2 \cdot HCl$
- **Molecular Weight**: 236.74 g/mol
- **Chemical Source**: Synthetic fine chemical (chiral synthesis of S-enantiomer from 2,3-dimethylbenzaldehyde via imidazole cyclization, asymmetric reduction and hydrochlorination; purified by recrystallization to ensure ultra-high optical purity (≥99.8%) and low impurity content; optimized process for excellent water solubility and formulation compatibility).
- **Product Trait**: White crystalline powder, practically odorless, slightly hygroscopic; **freely soluble in water** (280 g/L at 25℃), freely soluble in ethanol/methanol, slightly soluble in organic solvents (acetone/ether); stable in dry, dark and neutral/weakly acidic environment, mild hydrolysis in alkaline/moist environment; no light sensitivity under normal storage conditions; optical purity remains stable without racemization.
- **Core Properties**: **Highly selective α_2-adrenergic agonist** (α_2/α_1 selectivity ratio = 1620:1, 8x higher than clonidine); potent sedative/analgesic effect with no respiratory depression (unique core advantage); fast onset (5-10 minutes), long duration of action (6-8 hours); reversible sedation (awaken quickly with stimulation); the gold standard for surgical anesthesia induction/maintenance and ICU sedation.
- **Main Application**: Pharmaceutical intermediate for human injectable sedative/analgesic formulations (operating room surgical anesthesia, ICU intensive care sedation, procedural sedation); pharmaceutical R&D reference reagent for α_2-adrenergic receptor and neuropharmacology research.

2. Technical Specifications (Pharmaceutical Grade, Complies with USP/EP/CP)

Item	Specification	Test Method
Appearance	White to off-white crystalline powder	Visual Inspection
Odor	Practically odorless	Olfactory Inspection
Assay (Dexmedetomidine Hydrochloride)	≥ 99.5%	HPLC
Optical Purity (S-enantiomer)	≥ 99.8%	Chiral HPLC
Loss on Drying	≤ 0.3%	105℃ constant weight method (2h)
Residue on Ignition	≤ 0.1%	600±25℃ ignition method
Heavy Metals (Pb)	≤ 2 ppm	AAS
Heavy Metals (As)	≤ 1 ppm	AFS
Related Substances	≤ 0.3%	HPLC
Chloride (Cl^-)	15.0-15.6%	Volumetric Method
Sulfate (SO_4^{2-})	≤ 0.02%	Turbidimetric Method
Melting Point	143-147℃	Melting Point Apparatus
pH Value (1% aqueous solution,25℃)	4.5-7.0	Digital pH Meter
Total Bacterial Count	≤ 5 CFU/g	Plate Count Method
E. coli	Negative	Microbiological Detection
Yeast & Mold	≤ 5 CFU/g	Plate Count Method
Particle Size	95% passing 100 mesh	Standard Sieve Method
Water Solubility (25℃)	≥ 250 g/L	Solubility Test
Bulk Density	1.18-1.22 g/cm³	Pycnometer Method

Item	Specification	Test Method
Hydrolysis Stability	≤ 0.2% related substances after 7 days (25℃, 60% RH)	HPLC

3. Product Advantages

1. **Ultra-High Selectivity**: a_2/a_1 selectivity ratio up to 1620:1, 8 times higher than clonidine; minimal a_1 receptor activation, no significant hypertension (initial phase), low cardiovascular adverse effects; the most selective a_2-agonist for clinical use.
2. **No Respiratory Depression**: Unique sedative/analgesic with no respiratory depression even at high clinical doses; safe for patients with respiratory insufficiency (COPD, asthma, postoperative respiratory depression); the first choice for ICU sedation and pediatric anesthesia.
3. **Reversible Sedation**: Sedation effect is fully reversible with mild stimulation; patients can be awakened quickly for clinical assessment (neurological examination, pain evaluation); improves clinical monitoring efficiency and patient safety.
4. **Ultra-High Optical Purity**: S-enantiomer optical purity ≥99.8%, no racemic isomer impurities; consistent pharmacological effect, low individual variation; ensures clinical efficacy and safety of finished formulations.
5. **Excellent Water Solubility**: Freely soluble in water (280 g/L at 25℃), the highest water solubility among a_2-agonists; easy to prepare high-concentration injectable formulations (100 μg/mL); no organic solvent required, reduces formulation irritation.
6. **Dual Sedative-Analgesic Effect**: Potent central sedation and mild analgesic effect; reduces the dosage of anesthetics/analgesics in surgical anesthesia; decreases opioid-related adverse effects (nausea, vomiting, respiratory depression).

4. Application Fields

4.1 Pharmaceutical Industry (Operating Room Anesthesia Formulations)

- **Anesthesia Induction/Maintenance**: Core raw material for 100 μg/mL injectable formulations; used for general anesthesia induction and maintenance in major surgery (abdominal, thoracic, neurological); reduces propofol/sevoflurane dosage, stable hemodynamics.
- **Regional Anesthesia Adjuvant**: Low-concentration (1 μg/mL) formulation as epidural/spinal anesthesia adjuvant; prolongs analgesia duration, reduces postoperative pain score, decreases opioid usage.

5. Usage & Formulation Guidelines

5.1 Recommended Dosage/Concentration (Pharmaceutical Formulations)

- **Anesthesia Induction**: 100 μg/mL injectable formulation, intravenous bolus 1 μg/kg over 10 minutes; followed by continuous infusion 0.2-0.7 μg/kg/h for maintenance.
- **ICU Sedation**: 4 μg/mL concentrated formulation, loading dose 1 μg/kg over 10 minutes; maintenance infusion 0.2-0.4 μg/kg/h (adjust according to sedation score).

6. Packaging & Storage

6.1 Packaging Specifications (Pharmaceutical Grade, Anti-Hygroscopic)

- 100 g/bottle: Amber glass pharmaceutical bottle with plastic inner cap + aluminum foil seal (laboratory/R&D/analytical use, light protection).
- 1 kg/bag: Aluminum foil vacuum bag with PE inner lining (small-batch production use).
- 5 kg/25 kg/drum: HDPE pharmaceutical-grade drum with aluminum foil inner lining + sealed plastic cover + outer carton (bulk industrial production use).
- Custom packaging (500 g/2 kg) available for R&D and custom formulation production needs.

7. Safety & Protection

- The product is a high-selectivity a_2-agonist toxic pharmaceutical intermediate with cardiovascular/neurological effects; **all operations must be conducted by trained professional personnel** with full specified PPE (N95 dust mask, chemical-resistant full face shield, nitrile rubber gloves, impermeable lab coat).
- Avoid direct contact with eyes/skin/respiratory tract; avoid inhaling dust and swallowing raw powder; operate in a well-ventilated dust-free fume hood.
- Monitor heart rate/blood pressure for personnel with prolonged operation time (>4 hours); take a rest every 2 hours for continuous operation.