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: 18 FEB 2026Version: V1.0

1. Product Overview

- **Product Name**: Ropivacaine Mesylate
- **CAS Number**: 132530-03-7
- **Molecular Formula**: $C_{17}H_{26}N_2O \cdot CH_4O_3S$
- **Molecular Weight**: 374.59 g/mol
- **Chemical Source**: Synthetic fine chemical (chiral synthesis from (S)-2-piperidinecarboxylic acid and 2,6-dimethylaniline via amidation, propylation and methanesulfonic acid salinization; purified by recrystallization to ensure ultra-high purity and low impurity content; optimized process for excellent water solubility and formulation compatibility for injectable preparations).
- **Product Trait**: White crystalline powder, practically odorless, slightly hygroscopic and light-sensitive; **freely soluble in water** (300 g/L at 25℃), freely soluble in ethanol/methanol, slightly soluble in organic solvents (acetone/ether); stable in dry, dark and weakly acidic environment, mild hydrolysis in alkaline/moist environment; good stability in pharmaceutical processing with light protection.
- **Core Properties**: Classic **long-acting amide local anesthetic (S-enantiomer)**; high selectivity for sensory nerve block, obvious sensory-motor block separation; low cardiac and central nervous system toxicity compared to bupivacaine; long duration of action (6-12 hours); the gold standard for clinical epidural anesthesia, peripheral nerve block and postoperative pain management.
- **Main Application**: Pharmaceutical intermediate for human injectable local anesthesia formulations (epidural block, brachial plexus block, intercostal nerve block); pharmaceutical R&D reference reagent for local anesthetic pharmacology and anesthesiology 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 (Ropivacaine Mesylate)	≥ 99.5%	HPLC
Loss on Drying	≤ 0.3%	105℃ constant weight method (2h, light protection)
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
Methanesulfonate ($CH_3SO_3^-$)	19.0-21.0%	Volumetric Method
Sulfate (SO_4^{2-})	≤ 0.02%	Turbidimetric Method
Melting Point	144-148℃	Melting Point Apparatus (light protection)
pH Value (1% aqueous solution,25℃)	4.0-6.0	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 (light protection)
Water Solubility (25℃)	≥ 290 g/L	Solubility Test

Item	Specification	Test Method
Bulk Density	1.21-1.25 g/cm³	Pycnometer Method
Hydrolysis Stability	≤ 0.2% related substances after 7 days (25℃, 60% RH, light protection)	HPLC

3. Product Advantages

1. **Sensory-Motor Block Separation**: High selectivity for sensory nerve fibers, weak block on motor nerve fibers; patients maintain limb movement while achieving pain relief, significantly improving postoperative mobility and recovery speed.
2. **Ultra-Low Cardiac Toxicity**: S-enantiomer structure with low affinity for cardiac sodium channels; far lower risk of cardiac arrhythmia and cardiac arrest than bupivacaine, higher clinical safety for high-dose administration.
3. **Excellent Water Solubility**: Freely soluble in water (300 g/L at 25℃), suitable for preparing high-concentration injectable formulations (0.5%-1.0%); no organic solvent required for basic formulations, reduces vascular/tissue irritation and formulation complexity.
4. **Long-Acting Analgesia**: Duration of action up to 6-12 hours at clinical doses; provides long-term pain relief for postoperative and chronic pain management, reduces the frequency of additional analgesia.

4. Application Fields

4.1 Pharmaceutical Industry (Clinical Local Anesthesia)

- **Epidural Anesthesia**: Core raw material for 0.5%-0.75% injectable formulations; used for obstetric labor analgesia, abdominal surgery and lower limb surgery epidural block; stable analgesic effect, low impact on maternal/fetal and hemodynamics.
- **Peripheral Nerve Block**: 0.25%-0.5% formulation for brachial plexus, intercostal, femoral and sciatic nerve block; precise sensory block, minimal motor function impairment, ideal for limb surgery anesthesia.

5. Usage & Formulation Guidelines

5.1 Recommended Dosage/Concentration (Pharmaceutical Formulations)

- **Epidural Anesthesia (Adult)**: 0.5%-0.75% injectable formulation, single dose 10-20 mL, maximum single dose 150 mg; continuous infusion 6-12 mL/h (0.1%-0.2%).
- **Peripheral Nerve Block (Adult)**: 0.25%-0.5% formulation, single dose 10-30 mL, adjusted according to block site and patient weight.
- **Postoperative Analgesia (Adult)**: 0.1%-0.2% dilute formulation, continuous epidural infusion 4-8 mL/h, titrate according to pain score.

6. Packaging & Storage

6.1 Packaging Specifications (Pharmaceutical Grade, Light Protection & 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 (light protection, small-batch production use).
- 5 kg/25 kg/drum: HDPE pharmaceutical-grade brown drum with aluminum foil inner lining + sealed plastic cover + outer carton (light protection, bulk industrial production use).
- Custom packaging (500 g/2 kg) available for R&D and custom formulation production needs (all **light protection**).

7. Safety & Protection

- The product is a long-acting amide local anesthetic toxic pharmaceutical intermediate with neurological/cardiac 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 with **light protection**.
- Monitor neurological/cardiac status for personnel with prolonged operation time (>4 hours); take a rest every 2 hours for continuous operation.