

Technical Data Sheet (TDS) - Montelukast Sodium

Revision Date: 28 FEB 2026 **Product Name:** Montelukast Sodium 孟鲁司特钠 **CAS Number:** 151767-02-1
Formula: C₃₅ H₃₉ NNaO₆ S **Molecular Weight:** 608.75 g/mol

1. Product Overview

Montelukast Sodium is a high-purity pharmaceutical-grade selective leukotriene receptor antagonist (LTRA), a core raw material for clinical anti-asthmatic and anti-allergic preparations. It exerts therapeutic effects by selectively blocking the cysteinyl leukotriene CysLT1 receptor, inhibiting the inflammatory effects of leukotrienes on the respiratory tract, reducing airway hyperresponsiveness, relieving bronchospasm and allergic rhinitis symptoms. It is a white crystalline powder with excellent water solubility, stable physical and chemical properties under recommended storage conditions, and is widely used in the production of oral solid, chewable and granule pharmaceutical preparations for the treatment of asthma and allergic rhinitis in adults and children.

2. Technical Specifications (Complies with USP 45 & ChP 2025)

Item	Specification
Appearance	White to off-white crystalline powder
Assay (on dry basis)	98.0 ~ 102.0%
Related Substances	Total ≤ 1.0%; Single Impurity ≤ 0.2%
Loss on Drying	≤ 0.5%
Residue on Ignition	≤ 0.1%
Heavy Metals (Pb)	≤ 5 ppm
Heavy Metals (As)	≤ 1 ppm
Sodium Content	3.6 ~ 4.0%
pH Value (1% aq. solution, 25°C)	6.5 ~ 8.5
Melting Point	Decomposes at ~146°C
Total Bacterial Count	≤ 100 CFU/g
E. coli/Salmonella	Negative
Water Solubility (25°C)	≥ 60 g/100 mL
Density (25°C, solid)	1.29-1.33 g/cm ³
Viscosity (5% aq. solution, 25°C)	30-80 mPa·s
Temperature Stability	Stable at 0-30°C (assay retention ≥ 98%)
pH Stability	Stable at pH 6.0-9.0 (activity retention ≥ 95%)

3. Product Advantages

- Highly Selective Receptor Antagonism:** Targets CysLT1 receptor specifically, strong anti-asthmatic and anti-allergic effect with clear mechanism of action.
- Good Safety Profile:** Low adverse reaction rate, only occasional mild headache, abdominal pain and other symptoms, no obvious drug interaction, good tolerance for long-term use.
- Excellent Solubility:** High water solubility, suitable for the preparation of various oral dosage forms including chewable tablets and granules for pediatric use.
- Broad Clinical Application:** Effective for chronic asthma prevention and treatment, exercise-induced bronchospasm prevention and allergic rhinitis, applicable to adults and children over 1 year old.
- High Purity & Stable Quality:** Pharmacopoeial grade purity, ultra-low impurity and heavy metal content, stable physical and chemical properties under recommended storage conditions.
- Convenient Administration:** Oral absorption is rapid and complete, no need for food matching, high patient compliance.

4. Application Fields

- Pharmaceutical Anti-asthmatic & Anti-allergic Preparations:** Production of 10mg adult oral tablets, 5mg pediatric chewable tablets, 4mg pediatric oral granules and oral dispersible tablets.



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>

- **Clinical Application:** Prevention and long-term treatment of chronic bronchial asthma, prevention of exercise-induced bronchospasm, relief of nasal congestion, sneezing and runny nose caused by allergic rhinitis in hospitals, clinics and family medicine.

5. Usage Methods

Dosage for Formulation (Adjust according to preparation type)

- **10mg Adult Oral Tablet:** Add 10mg of Montelukast Sodium per tablet, mixed with lactose monohydrate (120mg), microcrystalline cellulose (70mg), cross-linked sodium carboxymethylcellulose (8mg) and magnesium stearate (1.5mg) for direct compression.
- **5mg Pediatric Chewable Tablet:** Add 5mg of Montelukast Sodium per tablet, mixed with mannitol (150mg), lactose (50mg), microcrystalline cellulose (30mg) and strawberry flavor (2mg) for wet granulation compression.
- **4mg Pediatric Granule:** Mix 4mg of Montelukast Sodium with maltodextrin (200mg), sucrose (80mg) and orange flavor (1mg), granulate and dry to prepare oral granules.

Processing Requirements

- Operate in a dry and well-ventilated environment (RH ≤ 50%) to prevent moisture absorption of the raw material.
- Ensure uniform mixing of the raw material and excipients to guarantee the content uniformity of the preparation, especially for pediatric low-dose preparations.
- Avoid high temperature (>60°C) during processing to prevent the degradation of active ingredients; the whole process complies with GMP pharmaceutical production specifications.

6. Packaging & Storage

Packaging Specifications

- 1 g / brown glass sealed bottle (R&D/laboratory use)
- 5 g / aluminum foil vacuum-sealed brown glass bottle (pilot production)
- 25 kg / HDPE light-proof sealed drum (industrial GMP production)
- 100 kg / stainless steel light-proof sealed drum (bulk pharmaceutical raw material)
- Custom GMP-compliant packaging available for bulk orders.

Storage Conditions

- Store in a cool, dry, dark warehouse at 15~25°C; avoid high temperature (>30°C) and direct sunlight.
- Keep the container tightly closed to prevent moisture absorption and oxidation; store separately from strong acids, strong oxidizing agents and high-humidity materials.
- **Shelf Life:** 36 months (unopened, under specified storage conditions); 6 months after opening (sealed, dry condition, used up as soon as possible).

Transportation

- Classified as non-hazardous pharmaceutical raw material; transport in compliance with national pharmaceutical raw material transportation regulations.
- Ambient temperature transport (15~25°C) with temperature monitoring; use shockproof, light-proof, moisture-proof packaging; avoid package collision and direct sunlight during transport.

7. Safety & Protection

- The product is a pharmaceutical raw material, not for direct human use; wear professional pharmaceutical PPE (nitrile rubber gloves, chemical safety goggles, dust mask) during handling.
- In case of skin contact: Rinse with plenty of running water and soap for 10 minutes; no special treatment for mild contact.
- In case of eye contact: Rinse with sterile water for injection for 15 minutes; consult a physician if irritation persists.
- Do not ingest; accidental oral intake may cause mild abdominal pain, headache—rinse mouth with water and consult a doctor if discomfort occurs.
- Operate in a well-ventilated GMP workshop with dry and light-proof facilities.

8. Quality Assurance

- The product is manufactured in accordance with GMP and ICH Q7 pharmaceutical raw material production guidelines, complying with ISO 9001 quality management system and ISO 14001 environmental management system standards.