纳维盈医化科技
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Technical Data Sheet (TDS)

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1. Product Overview

- **Product Name**: Desloratadine
- **CAS Number**: 100643-71-8
- **Molecular Formula**: C_{19} H_{19} ClN_2
- **Molecular Weight**: 310.82 g/mol
- **Chemical Source**: Synthetic fine chemical (synthesized via chlorination, cyclization and piperidine coupling; purified by recrystallization to ensure high purity and low impurity content; optimized process for good formulation compatibility for oral antiallergic preparations).
- **Product Trait**: White to off-white crystalline powder, practically odorless, slightly hygroscopic and light-sensitive; freely soluble in methanol/ethanol/chloroform, slightly soluble in water; stable in dry, dark and neutral/weakly acidic environment; good stability in pharmaceutical processing with light protection.
- **Core Properties**: **Second-generation non-sedating antihistamine**; highly selective H1 histamine receptor antagonist, blocks histamine binding to H1 receptors to inhibit allergic reactions; no significant central nervous system penetration, non-sedating at clinical doses; fast onset of action (30 minutes), long duration (24 hours); the classic pharmaceutical raw material for treating allergic rhinitis, chronic idiopathic urticaria and allergic dermatitis in adults and children.
- **Main Application**: Pharmaceutical intermediate for human oral antiallergic formulations (tablets, syrups, oral drops); pharmaceutical R&D reference reagent for allergy pharmacology and antihistamine research; analytical reference material for pharmaceutical quality inspection of antiallergic products.

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 (Desloratadine)	≥ 99.0%	HPLC
Loss on Drying	≤ 0.5%	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	≤ 0.5%	HPLC
Sulfate (SO_4^{2-})	≤ 0.02%	Turbidimetric Method
pH Value (1% methanol suspension,25℃)	6.0-8.0	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)
Solubility in Methanol	Freely soluble	Solubility Test
Bulk Density	1.28-1.32 g/cm³	Pycnometer Method
Photostability	≤ 0.3% related substances after 7 days (25℃, light exposure)	HPLC
Melting Point	145-151℃	Melting Point Apparatus (light protection)

3. Product Advantages

1. **Non-Sedating Antiallergic Effect**: Highly selective peripheral H1 receptor antagonist, no significant blood-brain barrier penetration; no sedation, drowsiness or cognitive impairment at clinical doses, suitable for daytime use.
2. **Fast & Long-Lasting Action**: Onset of antiallergic effect within 30 minutes of oral administration; 24-hour duration of action, once-daily dosing, high patient compliance.
3. **Broad Antiallergic Efficacy**: Effective for allergic rhinitis (sneezing, runny nose, nasal congestion), chronic urticaria (wheals, pruritus) and allergic dermatitis; inhibits both early and late allergic reactions.
4. **Pharmaceutical Grade Purity**: Assay ≥99.0%, related substances ≤0.5%, meets USP/EP/CP pharmacopoeia standards; ultralow heavy metal and microbial limits, suitable for clinical use for adults and pediatric patients (2 years old and above).
5. **Good Formulation Compatibility**: Freely soluble in organic solvents, slightly soluble in water; compatible with common oral pharmaceutical excipients; easy to prepare tablets, syrups and oral drops for different populations.
6. **Stable Storage Property**: 36-month shelf life under sealed, dark and dry conditions; slightly hygroscopic with no significant impact on quality; good stability in pharmaceutical processing.

4. Application Fields

4.1 Pharmaceutical Industry (Oral Antiallergic Formulations)

- **Allergic Rhinitis**: Core raw material for 5mg oral tablets/capsules; first-line treatment for seasonal and perennial allergic rhinitis; relieves sneezing, runny nose, nasal itching and ocular symptoms.
- **Chronic Idiopathic Urticaria**: Formulation for treating chronic spontaneous urticaria; relieves pruritus and wheal formation, long-term maintenance treatment available.
- **Pediatric Antiallergic Preparations**: 0.5mg/mL oral syrups/drops for children aged 2-12 years; accurate dosage, good palatability, high compliance.
- **Other Allergic Diseases**: Formulation development for allergic conjunctivitis, atopic dermatitis and food allergy auxiliary treatment.

5. Usage & Formulation Guidelines

5.1 Recommended Dosage/Concentration (Pharmaceutical Formulations)

- **Adult Tablets/Capsules**: 5mg per unit; once daily, oral administration, no food effect on absorption.
- **Pediatric Syrup**: 0.5mg/mL concentration; 2-5 years old: 2.5mg once daily; 6-12 years old: 5mg once daily.
- **Oral Drops**: 0.5mg/mL concentration; pediatric dosage based on body weight (0.25mg/kg once daily).

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 second-generation antihistamine pharmaceutical intermediate with mild irritant effects; **all operations must be conducted by trained professional personnel** with full specified PPE (dust mask, safety goggles, nitrile gloves, anti-chemical 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**.