Technical Data Sheet (TDS)

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1. Product Overview

- **Product Name**: Dyclonine Hydrochloride
- **CAS Number**: 536-43-6
- **Molecular Formula**: $C_{18}H_{27}NO_2 \cdot HCl$
- **Molecular Weight**: 325.88 g/mol
- **Chemical Source**: Synthetic fine chemical (synthesized from 4-hydroxybenzophenone via etherification, amination and hydrochlorination; purified by recrystallization and light protection processing; high-purity synthesis ensures low impurity content and good topical anesthetic activity).
- **Product Trait**: White crystalline powder, slightly aromatic, slightly hygroscopic and light-sensitive; soluble in water, freely soluble in ethanol/methanol/chloroform, slightly soluble in organic solvents (acetone/ether); stable in dry, dark and acidic environment, mild hydrolysis in alkaline/moist environment; no systemic absorption in topical/mucosal use (core safety characteristic).
- **Core Properties**: Classic non-narcotic topical surface anesthetic with **low systemic toxicity and long-lasting effect**; fast onset (1-3 minutes), long duration of action (2-4 hours); strong mucosal/skin surface anesthetic effect, no irritation to normal tissue at clinical concentration; no systemic absorption, safe for long-term topical use.
- **Main Application**: Pharmaceutical intermediate for human topical/mucosal anesthetic formulations (oral, throat, genital, skin); raw material for medical device coating anesthetic (endoscope, catheter); raw material for oral care products (anti-sensitive toothpaste); pharmaceutical R&D reference reagent for surface anesthetic 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	Slightly aromatic, practically odorless	Olfactory Inspection
Assay (Dyclonine Hydrochloride)	≥ 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)	≤ 5 ppm	AAS
Heavy Metals (As)	≤ 1 ppm	AFS
Related Substances	≤ 0.5%	HPLC
Chloride (Cl^-)	10.8-11.4%	Volumetric Method
Sulfate (SO_4^{2-})	≤ 0.05%	Turbidimetric Method
Melting Point	175-179℃	Melting Point Apparatus (light protection)
pH Value (1% aqueous solution,25℃)	4.0-6.0	Digital pH Meter
Total Bacterial Count	≤ 10 CFU/g	Plate Count Method
E. coli	Negative	Microbiological Detection
Yeast & Mold	≤ 10 CFU/g	Plate Count Method
Particle Size	95% passing 80 mesh	Standard Sieve Method (light protection)
Water Solubility (25℃)	≥ 8 g/L	Solubility Test
Ethanol Solubility	Freely soluble	Pharmacopoeia Method
Bulk Density	1.22-1.26 g/cm³	Pycnometer Method

Item	Specification	Test Method
Hydrolysis Stability	≤ 0.3% related substances after 7 days (25℃, 60% RH, light protection)	HPLC

3. Product Advantages

1. **Low Systemic Toxicity**: No systemic absorption in topical/mucosal use at clinical concentration; no cardiac/central nervous system toxicity, no addiction, safe for pregnant women, children and the elderly; the gold standard for topical surface anesthesia.
2. **Fast Onset & Long-Lasting Effect**: Onset in 1-3 minutes, duration of action up to 4 hours; longer anesthetic effect than lidocaine/benzocaine, reduces repeated medication frequency, improves patient comfort.
3. **Good Tissue Compatibility**: No irritation to normal skin/mucosa at clinical concentration (0.5-2%); mild stimulation only at high concentration (>5%), suitable for sensitive mucosa (oral, genital, ocular conjunctiva).
4. **Wide Solubility Range**: Soluble in water and freely soluble in organic solvents (ethanol/methanol); compatible with water-based, oil-based and alcohol-based formulations, easy to prepare gels, sprays, creams, solutions and coatings.

4. Application Fields

4.1 Pharmaceutical Industry (Topical/Mucosal Anesthetic Formulations)

- **Oral/Throat Anesthesia**: Core raw material for 0.5-1% spray/solution formulations; used for oral ulcer, pharyngitis, tonsillitis pain relief, and pre-anesthesia for oral/throat minor procedures (biopsy, tooth extraction).
- **Genital Mucosa Anesthesia**: 1% gel/cream formulations for genital herpes, condyloma acuminatum pain relief and pre-anesthesia for gynecological/urological minor procedures; no systemic absorption, safe for intimate area use.

5. Usage & Formulation Guidelines

5.1 Recommended Dosage/Concentration (Pharmaceutical Formulations)

- **Oral/Throat Anesthesia**: 0.5-1.0% spray/solution, spray 1-2 times each time, use every 2-4 hours if necessary; avoid swallowing large amounts.
- **Genital Mucosa Anesthesia**: 1.0% gel/cream, apply an appropriate amount to the affected area, keep for 1-2 minutes before procedure; wash with water after use.
- **Skin Anesthesia**: 1.0-2.0% cream/ointment, apply a thin layer to the affected area, cover with gauze if necessary; change dressing every 4 hours.
- **Medical Device Coating**: 0.5% ethanol solution, soak the device surface for 5-10 minutes, air dry before use; no rinsing required.

6. Packaging & Storage

6.1 Packaging Specifications (Pharmaceutical Grade, Light Protection & Anti-Hygroscopic)

- 100 g/bottle: Brown 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 low-toxic topical anesthetic pharmaceutical intermediate with mild skin irritation/sensitization; **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 and respiratory tract; avoid inhaling dust and swallowing raw powder; operate in a well-ventilated dust-free fume hood with light protection.
- Avoid repeated skin contact to prevent allergic sensitization; if skin rash/irritation occurs during operation, stop immediately and seek medical advice.