

Technical Data Sheet (TDS)

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1. Product Overview

- Product Name: Eperisone Hydrochloride (盐酸依培松)
- CAS Number: 5056-23-9
- Formula: $C_{17}H_{25}NO \cdot HCl$
- Molecular Weight: 295.85 g/mol
- Chemical Classification: Skeletal muscle relaxant; piperidinopropiophenone derivative
- Product Grade: Pharmaceutical Grade (EP/USP/CP Compliant)
- Product Characteristics: High-purity white crystalline powder; core API for skeletal muscle relaxant drugs; acts on both central and peripheral nervous systems to relieve muscle spasm and pain; good water solubility; stable under controlled storage conditions; strict impurity and heavy metal control for pharmaceutical use; low acute toxicity at occupational exposure levels; no significant side effects at clinical therapeutic doses.

2. Technical Specifications (EP 10.0 / USP 45 / CP 2020)

Item	Specification
Appearance	White to off-white crystalline powder
Assay (on dry basis)	$\geq 98.5\%$
Loss on Drying	$\leq 0.5\%$
Residue on Ignition	$\leq 0.1\%$
Heavy Metals (Pb)	≤ 5 ppm
Heavy Metals (As)	≤ 1 ppm
Related Substances	Each impurity $\leq 0.5\%$; Total $\leq 1.0\%$
Melting Point	175-179°C
pH Value (1% aq. solution, 25°C)	4.0-6.0
Solubility	Soluble in water, freely soluble in methanol
Chloride Content	11.8-12.8%
Sulfate Content	$\leq 0.03\%$
Particle Size	90% passing 100 mesh
Optical Rotation	$0^\circ \pm 1^\circ$ (1% in methanol)

3. Product Advantages

1. **International Pharmacopoeial Compliance:** Meets EP/USP/CP global pharmaceutical standards; ultra-low related substances and heavy metal content; batch-to-batch consistency, suitable for GMP pharmaceutical formulation and commercial production of muscle relaxant drugs.
2. **Double-Action Muscle Relaxation:** Acts on both central nervous system (inhibits spinal reflex) and peripheral smooth muscle (relaxes vascular smooth muscle); relieves muscle spasm and pain with rapid onset and long duration; improves blood circulation at the affected part.
3. **High Purity & Clinical Safety:** Pharmaceutical grade with $\geq 98.5\%$ assay; strict control of toxic impurities and heavy metals; good clinical tolerability; no significant side effects (e.g., muscle weakness) at therapeutic doses; low risk of drug interactions.
4. **Excellent Solubility & Stability:** Good water solubility (15.2 g/100 mL) suitable for oral solid and liquid dosage forms; 24-month shelf life under dry, cool storage; slight hygroscopy (controllable with sealed packaging); no chemical degradation under normal pharmaceutical processing conditions.
5. **GMP Manufacturing:** Produced in GMP/ISO 9001 certified facility; complete raw material traceability; strict in-process quality control for all key parameters; compliant with international pharmaceutical quality standards for neurological drug production.

4. Application Fields



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- **Pharmaceutical Formulation:** Production of oral skeletal muscle relaxant drugs (tablets, capsules, oral solutions) for clinical treatment of muscle spasm/pain caused by cervical spondylosis, lumbar disc herniation, myositis and other musculoskeletal diseases.
- **Pharmaceutical R&D:** Research on new muscle relaxant formulations (sustained-release, sublingual); preclinical/clinical research on postoperative muscle spasm relief; drug combination research for chronic pain treatment.
- **Academic Research:** Neuroscience research on muscle relaxation mechanism; research on spinal reflex regulation; development of new muscle relaxants with high selectivity and low side effects.

5. Usage Methods

- **Formulation Compatibility:** Suitable for oral solid dosage forms (tablets, capsules) and liquid dosage forms (oral solutions); compatible with common pharmaceutical excipients (microcrystalline cellulose, lactose, starch, magnesium stearate); no solubilizer required for aqueous formulations (good water solubility).
- **Typical Dosage (Formulated Drug):** Adult oral dosage 50-100 mg per time, 3 times a day; adjust dosage according to patient's condition and age – **clinical prescription only, no self-medication.**
- **Processing Precautions:** Process in dust-free, low-humidity (<60%) GMP workshop; use closed handling systems to avoid dust inhalation and hygroscopy; avoid contact with strong acids/bases and high temperature (>60°C); maintain normal temperature (15-25°C) during processing.

6. Packaging & Storage

6.1 Packaging Specifications

- 100 g/bottle (HDPE bottle with aluminum foil moisture-proof seal, inner plastic liner)
- 500 g/bottle (HDPE bottle with moisture-proof seal)
- 1 kg/drum (sealed HDPE drum with inner plastic bag)
- 5 kg/drum (fiber drum with HDPE inner liner, moisture-proof)
- Custom GMP-compliant packaging for industrial bulk orders (per customer requirements)

6.2 Storage Conditions

- Store in a **cool, dry, well-ventilated warehouse** at $\leq 25^{\circ}\text{C}$; keep container tightly sealed to prevent moisture absorption and dust contamination; avoid direct sunlight and high humidity (>60%).
- Incompatibilities: Store separately from strong acids, strong bases, oxidizing agents, food and feed materials.
- Shelf Life: **24 months** (unopened, under specified storage conditions); 6 months after opening (resealed, dry, cool storage).

6.3 Transportation

- Classified as UN 2811 (Class 6.1 Toxic Substance); transport with sealed, moisture-proof packaging; maintain temperature $\leq 25^{\circ}\text{C}$ during transport.
- Mark with GHS hazard labels and UN 2811; avoid direct sunlight, high temperature, collision and vibration during transport; do not transport with strong acids/bases/oxidizing agents, food or feed.
- Comply with IMDG/IATA/ADR regulations for Class 6.1 toxic solids; use ordinary freight vehicles with good sealing performance.

7. Quality Assurance

- Manufactured in **GMP and ISO 9001 certified** production facility; strict in-process quality control (IPC) for all production steps; all test parameters meet EP/USP/CP pharmacopoeial standards.
- Each batch is accompanied by a batch-specific **Certificate of Analysis (COA)** with full test results; quality records retained for 5 years (per GMP requirements).
- Complete raw material and production traceability system; professional technical support for pharmaceutical formulation development, process optimization and quality control guidance for muscle relaxant drug production.
- Regular product quality review and stability study; continuous improvement of production process to ensure batch-to-batch consistency and long-term stability.