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Technical Data Sheet (TDS)

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1. Product Overview

- Product Name: Mildronate (米尔膦酸盐)
- CAS Number: 83700-79-0
- Formula: $C_6H_{11}NO_4$
- Molecular Weight: 161.16 g/mol
- Chemical Classification: Metabolic modulator; gamma-butyrobetaine hydroxylase inhibitor
- Product Grade: Pharmaceutical Grade (EP/USP/CP Compliant)
- Product Characteristics: High-purity white crystalline powder; core API for cardioprotective and anti-ischemic drugs; regulates cellular energy metabolism; protects cardiac and skeletal muscle from ischemia/reperfusion injury; excellent water solubility (38.5 g/100 mL); highly stable under normal storage conditions; non-toxic, fully biodegradable; strict impurity and heavy metal control for pharmaceutical use.

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

Item	Specification	Test Method
Appearance	White crystalline powder or crystals	Visual Inspection
Assay (on dry basis)	≥ 98.5%	High Performance Liquid Chromatography (HPLC)
Loss on Drying	≤ 0.5%	105℃, 2h Gravimetry
Residue on Ignition	≤ 0.1%	550℃ Ignition Method
Heavy Metals (Pb)	≤ 5 ppm	Atomic Absorption Spectrometry (AAS)
Heavy Metals (As)	≤ 1 ppm	Atomic Fluorescence Spectrometry (AFS)
Related Substances	Each impurity ≤ 0.5%; Total ≤ 1.0%	HPLC
Melting Point	170-174℃	Capillary Melting Point Method
pH Value (1% aq. solution, 25℃)	6.0-7.5	Digital pH Meter
Solubility	Freely soluble in water, slightly soluble in ethanol	Pharmacopoeial Solubility Test
Chloride Content	≤ 0.01%	Volumetric Titration
Sulfate Content	≤ 0.03%	Volumetric Titration
Particle Size	90% passing 100 mesh	Sieve Analysis
Optical Rotation	+19° to +21° (10% in water)	Polarimetry

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 cardioprotective drugs.
2. **Unique Metabolic Modulation**: Gamma-butyrobetaine hydroxylase inhibitor; regulates cellular energy metabolism (car nitine synthesis); protects cardiac and skeletal muscle from ischemia and reperfusion injury; improves exercise tolerance; no direct hemodynamic effects, high clinical safety.
3. **Superior Safety Profile**: Extremely low acute toxicity (oral LD_{50} = 5000 mg/kg); no chronic toxic effects; no reproductive/developmental harm; mild eye irritation only at high concentrations; fully biodegradable and environmentally friendly.
4. **Excellent Solubility & Stability**: Freely soluble in water (38.5 g/100 mL) suitable for oral and injectable dosage forms; 36-month long shelf life at ≤30℃; highly stable (no chemical degradation under normal storage/processing); no significant hygroscopy.

5. **Flexible Manufacturing & Application**: Produced in GMP/ISO 9001 certified facility; non-hazardous classification (no special transport/handling restrictions); compatible with all common pharmaceutical dosage forms; suitable for both human and veterinary pharmaceutical production (with approval).

4. Application Fields

- **Pharmaceutical Formulation**: Production of oral and injectable cardioprotective drugs (tablets, capsules, injections, oral solutions) for clinical treatment of myocardial ischemia, heart failure, cerebral ischemia and peripheral vascular disease; also used for sports medicine (improving exercise tolerance).
- **Pharmaceutical R&D**: Research on new cardiovascular drug formulations (sustained-release, long-acting injectables); preclinical/clinical research on myocardial infarction and stroke treatment; drug combination research for cardiovascular disease; development of new metabolic modulators for organ protection.
- **Academic Research**: Biomedical research on cellular energy metabolism and ischemia/reperfusion injury; research on carnitine synthesis pathway; development of new drugs for cardiovascular and cerebrovascular diseases; sports medicine research on exercise physiology.

5. Usage & Formulation Guidelines

- **Formulation Compatibility**: Suitable for **oral solid/liquid dosage forms** (tablets, capsules, oral solutions) and **injectable formulations** (intravenous/intramuscular injections); excellent water solubility (no solubilizer required for aqueous formulations); compatible with common pharmaceutical excipients (microcrystalline cellulose, lactose, mannitol, sodium chloride, water for injection).
- **Typical Dosage (Formulated Drug)**:
  - Oral: 500-1000 mg/day (divided doses) for cardiovascular disease
  - Injectable: 500 mg/day (intravenous injection) for acute myocardial ischemia – **clinical prescription only, adjust dosage according to patient condition**.

6. Packaging & Storage

6.1 Packaging Specifications

- **Oral Grade**:
  - 100 g/bottle (HDPE bottle with moisture-proof seal)
  - 1 kg/5 kg/drum (sealed HDPE/fiber drums with inner plastic bag)
- **Injectable Grade**:
  - 50 g/250 g/bottle (amber glass bottle with rubber stopper + aluminum crimp seal, pyrogen-free)
  - Custom GMP-compliant/pyrogen-free packaging for industrial bulk injectable grade orders.

6.2 Storage Conditions

- **General Storage**: Store in a cool, dry warehouse at ≤30℃; keep container tightly sealed; avoid direct sunlight and high humidity (>70%); **36-month shelf life** (unopened, specified conditions).
- **Injectable Grade**: Store at 2-8℃ for long-term storage (extended shelf life); avoid freeze-thaw cycles; resealed after opening (6 months shelf life for opened packaging).

6.3 Transportation

- **Oral Grade**: Non-hazardous goods; ordinary freight transport (no UN number/hazard labels); transport at ≤30℃; use sealed packaging; avoid direct sunlight and high temperature.

7. Quality Assurance

- Manufactured in **GMP and ISO 9001 certified** production facility (including clean room for injectable grade); strict in-process quality control for all production steps; all test parameters meet EP/USP/CP pharmacopoeial standards.
- Each batch (oral/injectable) 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 **oral/injectable formulation development**, process optimization and GMP compliance guidance; provide technical solutions for cardiovascular drug production.