

Technical Data Sheet (TDS)

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1. Product Overview

- **Product Name:** Mexidol
- **CAS Number:** 53378-72-8
- **Molecular Formula:** C₁₀ H₁₅ NO₃
- **Molecular Weight:** 197.23 g/mol
- **Chemical Source:** Synthetic pharmaceutical raw material (synthesized from 2,5-diethyl-3-hydroxy-6-methylpyridine and succinic anhydride via esterification; purified by recrystallization and column chromatography to ensure high purity and low impurity content; optimized synthetic process for good formulation compatibility for oral and injectable pharmaceutical preparations).
- **Product Trait:** White to off-white crystalline powder, practically odorless, slightly hygroscopic and slightly light-sensitive; freely soluble in water/methanol, soluble in ethanol; stable in dry, dark and neutral/weakly acidic environment, mild hydrolysis in strong alkaline environment; good stability in pharmaceutical processing with low temperature (≤80°C).
- **Core Properties: Potent central nervous system (CNS) protective agent** with multiple pharmacological effects (antioxidant, anti-hypoxic, anti-free radical, membrane-stabilizing); inhibits lipid peroxidation, improves cerebral blood circulation and mitochondrial function; reduces neuronal damage caused by cerebral ischemia, craniocerebral injury and neurotoxicity; low systemic side effects at clinical doses, high safety for long-term use; the classic pharmaceutical raw material for clinical treatment of cerebrovascular and neurological diseases.
- **Main Application:** Pharmaceutical raw material for human oral/injectable formulations (tablets, injections, capsules); treatment of cerebral ischemia, craniocerebral trauma, cerebral circulation disorders and neurosis; pharmaceutical R&D reference reagent for neuroscience, neuroprotective pharmacology and cerebrovascular drug research; analytical standard for pharmaceutical quality inspection and clinical testing.

2. Technical Specifications (Pharmaceutical Grade, Complies with USP/EP/CP)

Item	Specification
Appearance	White to off-white crystalline powder
Odor	Practically odorless
Assay (Mexidol)	98.5-101.5%
Melting Point	105-109°C
Loss on Drying	≤ 0.5%
Residue on Ignition	≤ 0.1%
Heavy Metals (Pb)	≤ 2 ppm
Heavy Metals (As)	≤ 1 ppm
Related Substances	≤ 0.5%
pH Value (1% aqueous solution, 25°C)	5.0-7.0
Solubility	Freely soluble in water; soluble in ethanol
Total Bacterial Count	≤ 10 CFU/g
E. coli	Negative
Yeast & Mold	≤ 10 CFU/g
Particle Size	95% passing 100 mesh
Bulk Density	1.12-1.16 g/cm ³
Photostability	≤ 0.3% related substances after 7 days (25°C, light exposure)
Water Solubility	≥ 50 g/L (25°C)

3. Product Advantages

1. **Multi-Effect Neuroprotection:** Integrates antioxidant, anti-hypoxic, anti-free radical and membrane-stabilizing effects; protects neuronal cells from multiple injury factors (ischemia,



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hypoxia, toxic damage); significantly improves neurological function recovery in clinical applications.

2. **Broad Clinical Efficacy:** Effective for a variety of cerebrovascular and neurological diseases (cerebral ischemia, craniocerebral trauma, cerebral circulation disorders, neurosis); suitable for both acute treatment and chronic maintenance therapy, high clinical application value.
3. **Dual Formulation Compatibility:** Suitable for **oral solid formulations** (tablets/capsules) and **injectable formulations** (injections); good water solubility ensures high bioavailability of injectable preparations, and good compatibility with common oral excipients for easy formulation.
4. **Pharmaceutical Grade High Purity:** Meets USP/EP/CP international pharmacopoeia standards; ultralow heavy metal, microbial and related substance limits; high assay (98.5-101.5%); suitable for GMP production of clinical oral and injectable pharmaceutical formulations.

4. Application Fields

4.1 Pharmaceutical Industry (Neuroprotective Formulations)

- **Injectable Formulations:** Core raw material for 50mg/100mg Mexidol injections; first-line treatment for acute cerebral ischemia, craniocerebral trauma and severe cerebral circulation disorders; intravenous/intramuscular administration, rapid onset of action.
- **Oral Tablets/Capsules:** 25mg/50mg Mexidol tablets/capsules for chronic cerebral circulation disorders, neurosis and post-stroke rehabilitation; oral administration, convenient for long-term maintenance therapy, 2-3 times daily.
- **Combination Formulations:** Adjuvant raw material for cerebrovascular combination formulations (with antiplatelet drugs, cerebral vasodilators); synergistic neuroprotective and blood circulation-improving effects, enhanced clinical efficacy for cerebrovascular diseases.

5. Usage & Formulation Guidelines

5.1 Recommended Dosage/Concentration (Pharmaceutical Formulations)

- **Injectable Formulation (Adult):** 50mg/100mg per ampoule (pure Mexidol); 50-200mg per day, intravenous/intramuscular injection, adjusted according to clinical condition.
- **Oral Tablets/Capsules (Adult):** 25mg/50mg per tablet/capsule (pure Mexidol); 50-150mg per day, divided into 2-3 doses, taken with water after meals.
- **Elderly Formulation:** Low-dose oral formulation (25mg) with dosage reduction by 30-50% according to physical condition, under medical supervision.

6. Packaging & Storage

6.1 Packaging Specifications (Pharmaceutical Grade, Moisture-Proof & Light-Protective)

- 100 g/bottle: Amber glass pharmaceutical bottle with aluminum foil seal and plastic inner cap (R&D/analytical use, moisture-proof + light protection).
- 1 kg/bag: Aluminum foil vacuum bag with PE inner lining (small-batch pharmaceutical production use, moisture-proof + light protection).
- 5 kg/25 kg/drum: HDPE brown pharmaceutical drum with aluminum foil inner lining and sealed plastic cover (bulk pharmaceutical production use, moisture-proof + light protection).
- Custom packaging (500 g/2 kg) available for R&D and custom formulation production needs (all **moisture-proof + light protection**).

7. Safety & Protection

- The product is a Class 6.1 toxic pharmaceutical raw material with mild gastrointestinal toxicity and serious eye irritation; **all operations must be conducted by trained professional personnel** with full specified PPE (N95 dust mask, chemical-resistant safety goggles, nitrile rubber gloves ≥ 0.20 mm, impermeable lab coat).
- Avoid direct contact with eyes, mucous membranes and respiratory tract; avoid inhaling dust and accidental swallowing; operate in a well-ventilated dust-free fume hood with mild light protection measures (amber equipment, blackout curtain).
- Monitor gastrointestinal function (nausea, abdominal discomfort) for personnel with prolonged handling exposure; take regular rest and medical check-ups.