

## Technical Data Sheet (TDS)

### 1. Product Overview

- Product Name: Sulpiride
- English Name: Sulpiride
- CAS Number: 156-71-8
- Formula: C<sub>15</sub> H<sub>23</sub>N<sub>3</sub>O<sub>4</sub>S
- Molecular Weight: 341.42 g/mol
- Product Characteristics: High-purity pharmaceutical grade Sulpiride is a white crystalline powder, a typical antipsychotic drug raw material acting on the dopamine D2 receptor. It has stable chemical properties, low impurity content, and meets international pharmaceutical standards. It is suitable for the production of oral solid preparations (tablets, capsules) and injections, with antipsychotic, antiemetic and antidepressant effects.

### 2. Technical Specifications (Complies with Industrial/Pharmaceutical Standards)

Item	Specification
Appearance	White to off-white crystalline powder
Assay (HPLC)	≥ 99.0%
Melting Point	177-181 °C
Loss on Drying	≤ 0.5%
Residue on Ignition	≤ 0.1%
Heavy Metals (Pb)	≤ 10 ppm
Related Substances (Individual)	≤ 0.1%
Related Substances (Total)	≤ 0.5%
pH Value (1% aqueous suspension, 25 °C)	5.0-7.0
Solubility	Freely soluble in DMF; slightly soluble in ethanol; slightly soluble in water
Particle Size	90% passing 100 mesh
Microbial Limit	Total Aerobic Microbial Count ≤ 100 CFU/g; Yeast & Mold ≤ 10 CFU/g; E. coli Negative

### 3. Product Advantages

1. **High Purity & Stable Quality:** Pharmaceutical grade with assay ≥ 99.0%, low related substances, batch-to-batch consistency, meeting USP/Ph. Eur. standards.
2. **Good Processability:** Uniform particle size, good flowability, suitable for direct compression, wet granulation and injection preparation.
3. **Stable Chemical Properties:** Resistant to light/heat under normal storage conditions, no easy degradation, 24-month long shelf life.
4. **Environmentally Friendly:** Fully biodegradable, no environmental pollution during production and use, no harm to aquatic organisms.
5. **Comprehensive Certification:** With complete COA, MSDS and DMF documents, meeting the import/export requirements of various countries.

### 4. Application Fields



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- **Pharmaceutical Production:** Core raw material for antipsychotic/antiemetic drugs, used to produce Sulpiride tablets, capsules, orally disintegrating tablets and injections, for the treatment of schizophrenia, depression, nausea and vomiting.
- **R&D Application:** Used in pharmaceutical research and development, biological experiments, clinical trial samples and neuropharmacology research.
- **Other Fields:** No non-pharmaceutical use; only for pharmaceutical manufacturing.

## 5. Usage Methods

- **Formulation Compatibility:** Compatible with common pharmaceutical excipients (lactose, microcrystalline cellulose, magnesium stearate, mannitol, hydroxypropyl methylcellulose).
- **Processing Conditions:** Process at 20-25°C, relative humidity ≤60%; avoid high temperature (>60°C) and strong acid/alkali contact during production.
- **Dosage in Formulation:** Adjust according to drug specifications (common specifications: 100mg, 200mg per tablet/capsule; 50mg/mL for injection).
- **Mixing Requirement:** Mix evenly with excipients (mixing time ≥15 minutes) to ensure content uniformity (RSD ≤2%).

## 6. Packaging & Storage

- **Packaging Specifications:**
  - 1 kg/bag (aluminum foil vacuum bag, HDPE drum outer packing)
  - 5 kg/drum (HDPE drum with aluminum foil inner lining, sealed)
  - 10 kg/drum (HDPE drum with aluminum foil inner lining, sealed)
  - Custom packaging available upon request (for large-scale production/R&D).
- **Storage Conditions:** Store in a cool, dark, well-ventilated warehouse at ≤30°C; keep container tightly closed; avoid direct sunlight/strong acid/alkali/oxidizing agents; relative humidity ≤60%.
- **Shelf Life:** 24 months (unopened, under specified storage conditions); 6 months after opening (seal tightly and store as required).
- **Transportation:** Non-hazardous goods; transport by ordinary closed vehicles; avoid direct sunlight, high temperature, collision and rain during transport.

## 7. Safety & Protection

- The product is a pharmaceutical raw material, **not for direct human/animal consumption.**
- Avoid direct contact with eyes and inhalation of large amounts of dust; wear safety glasses and nitrile rubber gloves for large-scale handling.
- In case of eye contact, rinse with plenty of water for 5-10 minutes; consult a doctor if irritation persists.
- If accidentally swallowed, rinse mouth with water and consult a doctor if discomfort occurs; do not induce vomiting.
- Non-combustible, no fire/explosion risk, no special fire prevention measures required.

## 8. Quality Assurance

1. Produced in accordance with ISO 9001 and GMP quality management system standards.
2. Each batch of product is tested and accompanied by a Certificate of Analysis (COA) to ensure compliance with industrial/pharmaceutical standards.
3. Provide complete technical documents including MSDS, TDS and DMF to meet customer's import/export and production needs.
4. Accept third-party inspection (SGS, Intertek, CNAS) for product quality and purity.
5. Provide professional technical support for formulation development, production process optimization and quality control.