

Technical Data Sheet (TDS)

Product Name: Risperidone

CAS Number: 106266-06-2

Product Number: RIS-20260225

Revision Date: 25 FEB 2026

1. Product Overview

Risperidone is a high-purity chiral pharmaceutical raw material, a second-generation atypical antipsychotic agent. It acts on both 5-hydroxytryptamine (5-HT) and dopamine (D2) receptors to exert antipsychotic effects, with low extrapyramidal side effects. Produced in accordance with pharmaceutical GMP and chiral synthesis standards, it has high purity, low impurity content and stable quality, suitable for the production of oral solid preparations (tablets, capsules), oral solutions and injectable formulations.

Key Attributes:

- Formula: $C_{23}H_{27}FN_4O_2$
- Molecular Weight: 410.49 g/mol
- Purity: $\geq 99.0\%$ (HPLC)
- Form: White crystalline powder (odorless)
- Optical Rotation: $[\alpha]_{20}^D$: -118° to -128° (1% in $CHCl_3$)

2. Technical Specifications (Pharmaceutical Grade)

Item	Specification
Appearance	White to off-white crystalline powder
Assay (HPLC)	$\geq 99.0\%$
Melting Point	169-173°C
Loss on Drying	$\leq 0.5\%$
Residue on Ignition	$\leq 0.1\%$
Heavy Metals (Pb)	≤ 10 ppm
Related Substances (Individual)	$\leq 0.1\%$
Related Substances (Total)	$\leq 0.5\%$
Optical Rotation	$[\alpha]_{20}^D$: -118° to -128° (1% in $CHCl_3$)
Solubility	Freely soluble in chloroform/methanol; slightly soluble in ethanol
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 & Chiral Purity:** Pharmaceutical grade with assay $\geq 99.0\%$, low related substances, meets USP/Ph. Eur./BP international standards.
2. **Stable Quality:** Produced under GMP conditions, strict batch-to-batch quality control, excellent consistency.
3. **Good Processability:** Uniform particle size, good flowability, suitable for direct compression, wet granulation and injectable formulation preparation.
4. **Comprehensive Certification:** Complies with major international pharmaceutical standards, with DMF, COA provided for each batch.
5. **Low Impurity Risk:** Full-process raw material inspection and finished product testing, no hazardous impurities.

4. Application Fields



NEWAY SINOPHC TECH. LIMITED

ADD:RM. 204, BUILDING 3, NO. 188, AONA RD., CHINA (SHANGHAI) PILOT FREE TRADE ZONE.
Email:marketing01@newayphc.com; Phone:+86-021-50350029 <https://www.newayphc.com>

- **Pharmaceutical Production:** Core raw material for antipsychotic drugs, used to produce risperidone tablets, capsules, orally disintegrating tablets, oral solutions and injectables. Indicated for the treatment of schizophrenia, bipolar disorder and irritability associated with autistic disorder.
- **R&D Application:** Used in pharmaceutical research and development, biological experiments, preclinical and clinical trial samples.
- **Scope of Use:** Only for pharmaceutical manufacturing (human medicine); not for direct use or other non-pharmaceutical purposes.

5. Usage & Processing Guidelines

- **Formulation Compatibility:** Compatible with common pharmaceutical excipients (lactose, microcrystalline cellulose, mannitol, magnesium stearate, hydroxypropyl methylcellulose).
- **Processing Conditions:** Process at 20-25°C, relative humidity ≤60%; avoid moisture and high temperature during granulation and tableting.
- **Dosage in Formulation:** Adjust according to drug specifications (common specifications: 0.5mg, 1mg, 2mg, 3mg, 4mg per tablet/capsule).
- **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 (25 kg) available upon request for large-scale production.

Storage Conditions

- **Temperature:** 2-8°C (refrigerated storage)
- **Humidity:** Relative humidity ≤60%
- **Other:** Keep in a cool, dry, dark place; seal tightly to avoid light, moisture and air contact; store separately from strong acids, strong bases and oxidizing agents.

Shelf Life

- 24 months (unopened, stored in accordance with the above conditions); 6 months after opening (seal and refrigerate after each use).

Transportation

- Class 9 hazardous goods; transport with temperature-controlled insulated vehicles (2-8°C).
- Avoid direct sunlight, rain, collision and rough handling; comply with international transport regulations (IMDG/IATA/ADR).

7. Safety & Handling

- The product is a pharmaceutical raw material, **not for direct human/animal consumption.**
- Wear PPE (chemical splash goggles, nitrile gloves, lab coat, N95 dust mask) during handling; avoid dust inhalation and eye/skin contact.
- Operate in a well-ventilated fume hood/area; do not eat, drink or smoke in the handling area.
- In case of accidental contact (eye/skin) or ingestion, take first aid measures as specified in the MSDS and seek medical attention immediately.
- Non-flammable, no open flame operation restrictions during normal handling.

8. Quality Assurance

1. Produced in accordance with **GMP** and ISO 9001 quality management system standards.
2. Each batch is accompanied by a **Certificate of Analysis (COA)** with complete test results.
3. Provide **DMF (Drug Master File)**, MSDS and other technical documents as required by customers.
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.