

Technical Data Sheet (TDS)

Version Date: 28 FEB 2026

1. Product Overview

- Product Name: Ziprasidone Hydrochloride (盐酸齐拉西酮)
- CAS Number: 103639-82-5
- Formula: $C_{21}H_{21}ClN_4O_2 \cdot HCl$
- Molecular Weight: 441.34 g/mol
- Chemical Classification: Atypical antipsychotic; benzisothiazolylpiperazine derivative
- Product Grade: Pharmaceutical Grade (EP/USP/CP Compliant)
- Product Characteristics: High-purity white crystalline powder; core API for oral atypical antipsychotic drugs; dual-acting serotonin/dopamine receptor antagonist; potent therapeutic effect for schizophrenia and bipolar mania; low risk of extrapyramidal symptoms and weight gain; sparingly soluble in water; stable under controlled storage conditions; strict impurity and heavy metal control for pharmaceutical use.

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	238-242°C
pH Value (1% aq. suspension, 25°C)	4.0-6.0
Solubility	Sparingly soluble in water, soluble in methanol
Chloride Content	15.8-16.8%
Sulfate Content	$\leq 0.03\%$
Particle Size	90% passing 100 mesh
Optical Rotation	$0^\circ \pm 1^\circ$ (1% in methanol)

3. Product Advantages

- 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.
- Superior Antipsychotic Activity:** Dual-acting 5-HT_{2A}/D₂ receptor antagonist; atypical antipsychotic with high therapeutic index; effective for schizophrenia and bipolar mania; low risk of extrapyramidal side effects (EPS) and metabolic disorders (weight gain/diabetes).
- High Purity & Safety:** Pharmaceutical grade with $\geq 98.5\%$ assay; strict control of toxic impurities and heavy metals; good clinical tolerability; no significant acute toxicity at occupational exposure levels.
- Stable Quality:** 24-month shelf life under dry, cool storage; slight hygroscopy (controllable with sealed packaging); no chemical degradation under normal pharmaceutical processing conditions (tablet/capsule production).
- 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.



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4. Application Fields

- **Pharmaceutical Formulation:** Production of oral antipsychotic drugs (tablets, capsules, oral dispersible tablets) for clinical treatment of schizophrenia and bipolar I disorder (manic episodes).
- **Pharmaceutical R&D:** Research on new antipsychotic formulations (sustained-release, sublingual); preclinical/clinical research on bipolar depression; drug combination research for treatment-resistant schizophrenia.
- **Academic Research:** Neuroscience research on serotonin/dopamine receptor pharmacology; schizophrenia pathogenesis research; development of new atypical antipsychotics with improved safety profiles.

5. Usage & Formulation Guidelines

- **Formulation Compatibility:** Suitable for solid oral dosage forms (tablets, capsules); compatible with common pharmaceutical excipients (microcrystalline cellulose, lactose, starch, magnesium stearate); solubilizers (e.g., cyclodextrins) required for aqueous formulations.
- **Typical Dosage (Formulated Drug):** Adult oral dosage 40-80 mg/day (divided doses); titrate dosage according to clinical response – **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.
- Regular product quality review and stability study; continuous improvement of production process to ensure batch-to-batch consistency and long-term stability.