

Technical Data Sheet (TDS)

Version Date: 28 FEB 2026

1. Product Overview

- Product Name: Ziprasidone Mesylate (齐拉西酮甲磺酸盐)
- CAS Number: 139106-27-9
- Formula: $C_{21}H_{21}N_4O_2 \cdot CH_3SO_3H$
- Molecular Weight: 464.51 g/mol
- Chemical Classification: Atypical antipsychotic; benzisothiazolylpiperazine derivative
- Product Grade: Pharmaceutical Grade (EP/USP/CP Compliant, Oral/Injectable Grade)
- Product Characteristics: High-purity white crystalline powder; core API for oral/injectable atypical antipsychotic drugs; dual-acting serotonin/dopamine receptor antagonist; excellent water solubility (suitable for injectable formulations); potent therapeutic effect for schizophrenia and bipolar mania; low risk of extrapyramidal symptoms; stable under controlled storage conditions; strict impurity and heavy metal control for pharmaceutical use (including injectable grade requirements).

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

Item	Specification
Appearance	White to pale yellow 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	201-205°C
pH Value (1% aq. suspension, 25°C)	3.5-5.5
Solubility	Soluble in water, freely soluble in methanol
Methanesulfonate Content	19.0-20.0%
Sulfate Content	$\leq 0.03\%$
Particle Size	90% passing 100 mesh
Optical Rotation	$0^\circ \pm 1^\circ$ (1% in methanol)
Bacterial Endotoxins	≤ 0.5 EU/mg (injectable grade)
Sterility	Complies (injectable grade)

3. Product Advantages

1. **Dual-Grade Compliance:** Meets EP/USP/CP standards for both oral and injectable pharmaceutical grade; ultra-low related substances/heavy metals; bacterial endotoxin and sterility compliant for injectable use; batch-to-batch consistency, suitable for GMP oral/injectable drug production.
2. **Excellent Water Solubility:** Superior aqueous solubility (8.5 g/100 mL) compared to hydrochloride salt; ideal for injectable antipsychotic formulations (intramuscular/intravenous); rapid onset of action for acute manic episodes and severe schizophrenia.
3. **Superior Antipsychotic Activity:** Dual-acting 5-HT_{2A}/D₂ receptor antagonist; atypical antipsychotic with high therapeutic index; effective for schizophrenia (positive/negative symptoms) and bipolar mania; low risk of extrapyramidal side effects (EPS) and metabolic disorders (weight gain/diabetes).
4. **High Purity & Safety:** Pharmaceutical grade with $\geq 98.5\%$ assay; strict control of toxic impurities, heavy metals and bacterial endotoxins (injectable grade); good clinical tolerability; no significant acute toxicity at occupational exposure levels.

5. **GMP Manufacturing:** Produced in GMP/ISO 9001 certified facility (including injectable drug production clean room); complete raw material traceability; strict in-process quality control compliant with injectable pharmaceutical production regulations.

4. Application Fields

- **Pharmaceutical Formulation:** Production of **oral and injectable** antipsychotic drugs (tablets, capsules, intramuscular injections) for clinical treatment of schizophrenia (positive/negative symptoms) and bipolar I disorder (acute manic episodes).
- **Pharmaceutical R&D:** Research on new antipsychotic formulations (long-acting injectables, oral dispersible tablets); preclinical/clinical research on acute severe schizophrenia; development of injectable antipsychotics with rapid onset of action.
- **Academic Research:** Neuroscience research on serotonin/dopamine receptor pharmacology; research on acute psychosis treatment; development of new water-soluble atypical antipsychotics.

5. Usage & Formulation Guidelines

- **Formulation Compatibility:** Suitable for **oral solid dosage forms** (tablets, capsules) and **injectable formulations** (intramuscular injections); compatible with common pharmaceutical excipients (microcrystalline cellulose, lactose, mannitol, sodium chloride); no solubilizer required for aqueous injectable formulations (due to excellent water solubility).
- **Typical Dosage (Formulated Drug):**
 - Oral: 40-80 mg/day (divided doses) for schizophrenia/bipolar mania
 - Injectable (IM): 10-20 mg every 2-4 hours (acute mania) – **clinical prescription only, injectable drug for hospital use only.**
- **Processing Precautions:**
 - Oral grade: Process in dust-free, low-humidity (<60%) GMP workshop; closed handling systems to avoid dust inhalation.

6. Packaging & Storage

6.1 Packaging Specifications

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

6.2 Storage Conditions

- **Oral Grade:** Store in a cool, dry, well-ventilated warehouse at ≤25°C; keep container tightly sealed; avoid direct sunlight/high humidity (>60%).
- **Injectable Grade:** Store in a **cool, dry, dark warehouse at 2-8°C**; pyrogen-free sealed packaging; avoid direct sunlight, high temperature and freeze-thaw cycles; separate storage from oral grade raw materials.

6.3 Transportation

- **Oral Grade:** UN 2811 (Class 6.1 Toxic Substance); transport at ≤25°C; sealed moisture-proof packaging; mark with GHS/UN labels.

7. Quality Assurance

- Manufactured in **GMP and ISO 9001 certified** production facility (including Class 100 clean room for injectable grade); strict in-process quality control for all key parameters (including bacterial endotoxin/sterility for injectable grade).
- 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 injectable drug requirements).
- Complete raw material/production traceability system; professional technical support for **oral/injectable formulation development**, process optimization and GMP injectable production compliance guidance.