Technical Data Sheet (TDS)

Vortioxetine Hydrobromide CAS:936128-06-4Version Date: 28 FEB 2026

1. Product Overview

- Product Name: Vortioxetine Hydrobromide (沃替西汀溴化氢)
- CAS Number: 936128-06-4
- Formula: $C_{18}H_{22}BrN_3O$
- Molecular Weight: 376.29 g/mol
- Chemical Classification: Serotonin modulator and stimulator (SMS); piperazine derivative
- Product Grade: Pharmaceutical Grade (EP/USP/CP Compliant)
- Product Characteristics: High-purity white crystalline powder; core API for antidepressant drugs; multi-mechanism serotonin modulator; potent therapeutic effect for major depressive disorder; good solubility in organic solvents; 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	Test Method
Appearance	White to off-white crystalline powder	Visual Inspection
Assay (on dry basis)	≥ 98.5%	High Performance Liquid Chromatography (HPLC)
Loss on Drying	≤ 0.5%	105℃, 2h Gravimetry
Residue on Ignition	≤ 0.1%	550℃ Ignition Method
Heavy Metals (Pb)	≤ 5 ppm	Atomic Absorption Spectrometry (AAS)
Heavy Metals (As)	≤ 1 ppm	Atomic Fluorescence Spectrometry (AFS)
Related Substances	Each impurity ≤ 0.5%; Total ≤ 1.0%	HPLC
pH Value (0.5% aq. suspension, 25℃)	4.0-6.0	Digital pH Meter
Solubility	Sparingly soluble in water, soluble in methanol	Pharmacopoeial Solubility Test
Melting Point	178-182℃	Capillary Melting Point Method
Chloride Content	≤ 0.01%	Volumetric Titration
Sulfate Content	≤ 0.03%	Volumetric Titration
Particle Size	90% passing 100 mesh	Sieve Analysis
Optical Rotation	0° ±1° (1% in methanol)	Polarimetry

3. Product Advantages

1. **International Pharmacopoeial Compliance**: Meets EP/USP/CP global standards; ultra-low related substances and heavy metal content; batch-to-batch consistency, suitable for GMP pharmaceutical formulation and commercial production.
2. **Multi-Mechanism Antidepressant Activity**: Unique serotonin modulator and stimulator (SMS); acts on multiple serotonin receptors; rapid onset of antidepressant effect; low risk of sexual dysfunction and weight gain (compared with traditional antidepressants).
3. **High Purity & Safety**: Pharmaceutical grade with ≥98.5% assay; strict control of toxic impurities and heavy metals; good tolerability at clinical therapeutic doses; no significant acute toxicity at occupational exposure levels.

4. **Stable Quality**: 24-month shelf life under dry, cool storage; slight hygroscopy (controllable with sealed packaging); no chemical degradation under normal pharmaceutical processing conditions.
5. **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.

4. Application Fields

- **Pharmaceutical Formulation**: Production of antidepressant drugs (tablets, capsules, oral dispersible tablets) for clinical treatment of major depressive disorder (MDD).
- **Pharmaceutical R&D**: Research on new antidepressant formulations (sustained-release, sublingual); preclinical and clinical research on bipolar depression; drug combination research for treatment-resistant depression.
- **Academic Research**: Neuroscience research on serotonin system and depression pathogenesis; development of new serotonin modulators; research on the mechanism of antidepressant drug action.

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); soluble in methanol/ethanol for organic solvent-based formulations.
- **Typical Dosage (Formulated Drug)**: Adult oral dosage 5-20 mg/day (once daily); 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℃); maintain normal temperature (15-25℃) 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 ≤25℃; 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 ≤25℃ during transport.

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).