

Technical Data Sheet (TDS)

Citalopram Hydrobromide CAS:59729-32-7 Version Date: 28 FEB 2026

1. Product Overview

- Product Name: Citalopram Hydrobromide (西酞普兰溴化氢)
- CAS Number: 59729-32-7
- Formula: C₂₀H₂₁FN₂O ·HBr
- Molecular Weight: 405.30 g/mol
- Chemical Classification: Selective Serotonin Reuptake Inhibitor (SSRI)
- Product Grade: Pharmaceutical Grade (EP/USP/CP Compliant)
- Product Characteristics: High-purity crystalline powder; potent antidepressant API; soluble in water and organic solvents; stable under controlled storage conditions; high batch-to-batch consistency

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%	HPLC
Melting Point	183-189 °C	Capillary Melting Point Method
Loss on Drying	≤ 0.5%	105 °C Gravimetry (2h)
Residue on Ignition	≤ 0.1%	550 °C Ignition Method
Heavy Metals (Pb)	≤ 10 ppm	AAS
Heavy Metals (As)	≤ 2 ppm	AFS
Related Substances	Each impurity ≤ 0.5%; Total ≤ 1.0%	HPLC
Halide Content (Br)	19.5-20.5% (dry basis)	Volumetric Titration
Optical Rotation	+12.0° to +14.0° (1% in water)	Polarimetry
pH Value (1% aq. solution)	4.0-6.0	Digital pH Meter
Solubility	Soluble in water, ethanol	Pharmacopoeial Solubility Test
Particle Size	90% passing 100 mesh	Sieve Analysis

3. Product Advantages

- International Pharmacopoeial Compliance:** Meets EP/USP/CP standards; low related substances and heavy metal content; suitable for GMP pharmaceutical formulation.
- Potent Antidepressant Activity:** Selective serotonin reuptake inhibitor (SSRI); high efficacy for major depressive disorder; low side effect profile compared to tricyclic antidepressants.
- Excellent Solubility:** Water-soluble (46 g/L) – suitable for both solid oral dosage forms and oral liquid formulations.
- Stable Quality:** 24-month shelf life under 2-8 °C storage; consistent assay and impurity profile across batches; no significant degradation under recommended conditions.
- GMP Manufacturing:** Produced in a GMP/ISO 9001 certified facility; complete raw material traceability; strict in-process quality control.

4. Application Fields

- Pharmaceutical Formulation:** Production of antidepressant drugs (tablets, capsules, oral solutions, dispersible tablets) for the treatment of major depressive disorder, panic disorder and social anxiety disorder.



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- **Pharmaceutical R&D:** Research on new SSRI formulations; preclinical/clinical research on mood disorders; drug-drug interaction studies.
- **Academic Research:** Serotonin receptor pharmacology; neuroscience research on depression and anxiety disorders.

5. Usage & Formulation Guidelines

- **Formulation Compatibility:** Suitable for all solid oral dosage forms (tablets, capsules, chewable tablets) and oral liquid formulations; no special solubilizers required for aqueous preparations.
- **Typical Dosage (Formulated Drug):** Adult oral dosage 20-40 mg/day (as citalopram base) – **dosage subject to pharmaceutical formulation and clinical prescription.**
- **Processing Precautions:** Process in a dust-free, GMP-compliant workshop; maintain low humidity (<60%); avoid contact with strong acids/bases/oxidizing agents; use closed handling systems to prevent dust generation.

6. Packaging & Storage

6.1 Packaging Specifications

- 100 g/bottle (HDPE bottle with aluminum foil seal, inner plastic liner)
- 500 g/bottle (HDPE bottle with aluminum foil seal)
- 1 kg/drum (HDPE drum with inner plastic bag, sealed)
- 5 kg/drum (fiber drum with HDPE inner liner, sealed)
- Custom GMP-compliant packaging available for industrial bulk orders

6.2 Storage Conditions

- Store in a cool, dry, dark warehouse at **2-8°C**; keep container tightly sealed to prevent moisture and light exposure.
- Protect from direct sunlight, high temperature (>25°C) and high humidity (>60%); do not freeze.
- Store separately from strong acids, strong bases, oxidizing agents, food and feed materials.
- Shelf Life: **24 months** (unopened, specified conditions); 6 months after opening (resealed, 2-8°C).

6.3 Transportation

- Classified as UN 2811 (Class 6.1 Toxic Substance); transport with insulated cold chain packaging (maintain 2-8°C).
- Use sealed, chemical-resistant packaging; mark with GHS hazard labels, UN number and cold chain instructions.
- Avoid collision, vibration, direct sunlight and high temperature during transport; comply with IMDG/IATA/ADR for Class 6.1 goods.

7. Quality Assurance

- Manufactured in a **GMP and ISO 9001 certified** production facility; strict in-process and finished product quality control.
- Each batch is tested for all quality parameters; a batch-specific Certificate of Analysis (COA) is provided with every shipment.
- Complete raw material and production traceability; quality records retained for 5 years (per GMP requirements).
- Technical support provided for formulation development, processing optimization and regulatory compliance.