

Technical Data Sheet (TDS)

Clonazepam CAS:1622-61-3 Version Date: 20 FEB 2026

1. Product Overview

- Product Name: Clonazepam (氯硝西洋)
- CAS Number: 1622-61-3
- Formula: C₁₅H₁₀CIN₃O₃
- Molecular Weight: 315.71 g/mol
- Chemical Classification: 1,4-Benzodiazepine derivative
- Product Grade: Pharmaceutical Grade (EP/USP/CP compliant)
- Product Characteristics: High-purity crystalline powder; potent anti-epileptic and anxiolytic active pharmaceutical ingredient (API); stable under controlled storage conditions; low water solubility, soluble in organic solvents.

2. Technical Specifications (Complies with 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	237-240°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
Related Substances	Each impurity ≤ 0.5%; Total ≤ 1.0%	HPLC
Chloride Content	9.5-10.5% (dry basis)	Volumetric Titration
Solubility	Sparingly soluble in water, soluble in ethanol	Pharmacopoeial Solubility Test
Particle Size	90% passing 100 mesh; 99% passing 80 mesh	Sieve Analysis
Optical Rotation	0° ± 1° (1% in DMSO)	Polarimetry

3. Product Advantages

- High Purity & Compliance:** Meets international pharmacopoeial standards (EP/USP/CP); low related substances, no detectable heavy metal excess; suitable for pharmaceutical formulation.
- Potent Pharmacological Activity:** Potent anti-epileptic (against absence seizures, myoclonic seizures) and anxiolytic effects; low effective dosage.
- Stable Quality:** Consistent batch-to-batch performance; stable for 24 months under recommended storage conditions (2-8°C).
- Controlled Particle Size:** Pharmaceutical-grade particle size distribution; suitable for various formulation processes (tablets, capsules, injections).
- Reliable Supply:** Industrial-scale production; strict quality control system (ISO 9001, GMP compliant).

4. Application Fields

- Pharmaceutical Formulation:** Production of anti-epileptic drugs (tablets, dispersible tablets, oral solutions); anxiolytic and sedative drug preparation; clinical use for epilepsy, panic disorder, and seizure control.



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- **Research & Development:** Pharmaceutical R&D for new benzodiazepine derivatives; preclinical and clinical research on neurological disorders.
- **Veterinary Medicine:** Small-scale use for veterinary seizure control (authorized formulations only).

5. Usage & Formulation Guidelines

- **Formulation Compatibility:** Suitable for solid oral dosage forms (tablets, capsules) and oral liquid formulations; requires solubilizers (e.g., propylene glycol, DMSO) for parenteral formulations.
- **Typical Dosage (Formulated Drug):** Adult oral dosage 0.5-2 mg/day (anti-epileptic); 0.25-1 mg/day (anxiolytic) – **dosage subject to pharmaceutical formulation and clinical prescription.**
- **Processing Precautions:** Process in a dust-free, GMP-compliant workshop; avoid dust generation; use closed handling systems; maintain low humidity (<60%) during processing.

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 packaging available for industrial orders (per GMP requirements).

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%).
- Store separately from strong acids, strong bases, oxidizing agents, and food/feed materials.
- Shelf Life: **24 months** (unopened, under specified storage conditions); 6 months after opening (if resealed and stored at 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 international transport regulations (IMDG/IATA/ADR).

7. Quality Assurance

- Manufactured in a **GMP-compliant** production facility; ISO 9001 quality management system certified.
- Each batch is tested for full quality parameters; accompanied by a Certificate of Analysis (COA) with batch-specific test results.
- Raw material traceability; complete production and quality control records (retained for 5 years).
- Technical support provided for formulation and processing optimization.