纳维盈医化科技
NEWAY SINOPHC TECH

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Technical Data Sheet (TDS)

Clozapine CAS:5786-21-0Version Date: 20 FEB 2026

1. Product Overview

- Product Name: Clozapine (氯氮平)
- CAS Number: 5786-21-0
- Formula: C18H19ClN4
- Molecular Weight: 326.83 g/mol
- Chemical Classification: Atypical antipsychotic (dibenzo[b,e][1,4]diazepine derivative)
- Product Grade: Pharmaceutical Grade (EP/USP/CP compliant)
- Product Characteristics: Yellow crystalline powder; potent atypical antipsychotic active pharmaceutical ingredient (API); selective serotonin/dopamine receptor antagonist; stable under controlled storage conditions; low water solubility, soluble in organic solvents; light-sensitive.

2. Technical Specifications (Complies with EP 10.0, USP 45, CP 2020)

Item	Specification	Test Method
Appearance	Yellow to pale yellow crystalline powder	Visual Inspection
Assay (on dry basis)	≥ 98.0%	HPLC
Melting Point	183-187℃	Capillary Melting Point Method
Loss on Drying	≤ 0.5%	105℃ Gravimetry (2h)
Residue on Ignition	≤ 0.1%	550℃ Ignition Method
Heavy Metals (Pb)	≤ 10 ppm	AAS
Related Substances	Each impurity ≤ 0.5%; Total ≤ 1.5%	HPLC
Chloride Content	10.8-11.5% (dry basis)	Volumetric Titration
Solubility	Sparingly soluble in water, soluble in chloroform/methanol	Pharmacopoeial Solubility Test
Particle Size	90% passing 100 mesh; 99% passing 80 mesh	Sieve Analysis
Color of Solution	Clear, pale yellow (1% in DMF)	Visual Inspection

3. Product Advantages

1. **International Pharmacopoeial Compliance**: Meets EP/USP/CP standards; low related substances and heavy metal content; suitable for GMP pharmaceutical formulation.
2. **Potent Atypical Antipsychotic Activity**: Selective 5-HT2A/D2 receptor antagonist; effective for treatment-resistant schizophrenia; lower risk of extrapyramidal side effects (EPS) compared to typical antipsychotics.
3. **Stable Quality & Batch Consistency**: Strict quality control; consistent assay and impurity profile across batches; stable for 24 months under recommended storage conditions.
4. **Pharmaceutical-Grade Properties**: Optimized particle size distribution; suitable for solid oral dosage forms (tablets, orally disintegrating tablets); light-resistant packaging options available.
5. **GMP Manufacturing**: Produced in a GMP-compliant facility; ISO 9001 certified; complete traceability of raw materials and production processes.

4. Application Fields

- **Pharmaceutical Formulation**: Production of atypical antipsychotic drugs (tablets, orally disintegrating tablets, oral suspensions) for the treatment of schizophrenia (including treatment-resistant schizophrenia).

- **Pharmaceutical R&D**: Research on new atypical antipsychotic formulations; preclinical/clinical research on psychiatric disorders (bipolar disorder, schizoaffective disorder).
- **Clinical Research**: Academic and pharmaceutical research on serotonin/dopamine receptor pharmacology; drug-drug interaction studies.

5. Usage & Formulation Guidelines

- **Formulation Compatibility**: Primarily for solid oral dosage forms (tablets, capsules); requires solubilizers (e.g., DMF, propylene glycol) for liquid oral formulations; not suitable for parenteral formulations (poor water solubility).
- **Typical Dosage (Formulated Drug)**: Adult oral starting dosage 25 mg/day, titrated up to 300-600 mg/day (schizophrenia) – **dosage subject to pharmaceutical formulation and clinical prescription** (monitoring required for clinical use).
- **Processing Precautions**: Process in a **light-free, dust-free, GMP-compliant** workshop; maintain low humidity (<60%); use closed handling systems to avoid dust generation and light exposure; avoid contact with strong acids/bases during processing.

6. Packaging & Storage

6.1 Packaging Specifications

- 100 g/bottle (amber glass bottle with aluminum foil seal, inner plastic liner – light-resistant)
- 500 g/bottle (amber glass bottle with aluminum foil seal)
- 1 kg/drum (opaque HDPE drum with inner plastic bag, sealed)
- 5 kg/drum (fiber drum with opaque HDPE inner liner, sealed)
- Custom light-resistant packaging available for industrial GMP orders.

6.2 Storage Conditions

- Store in a **cool, dry, dark warehouse at 15-25℃**; use light-resistant packaging; keep container tightly sealed to prevent moisture and light exposure.
- Protect from direct sunlight, high temperature (>30℃), and high humidity (>60%); do not freeze.
- Store separately from strong acids, strong bases, oxidizing agents, food, feed, and unrelated pharmaceutical raw materials.
- Shelf Life: **24 months** (unopened, under specified storage conditions); 3 months after opening (if resealed and stored at 15-25℃ in dark).

6.3 Transportation

- Classified as UN 2811 (Class 6.1 Toxic Substance); transport with opaque, sealed packaging to avoid light exposure.
- Maintain transport temperature at 15-25℃; avoid direct sunlight, high temperature, and moisture; comply with international transport regulations (IMDG/IATA/ADR) for Class 6.1 goods.
- Mark packaging with GHS hazard labels, UN number, "Keep in Dark" and "Store at 15-25℃" instructions.

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 full quality parameters; a batch-specific Certificate of Analysis (COA) is provided with all shipments.
- Raw material traceability; complete production and quality records retained for 5 years (per GMP requirements).
- Technical support provided for formulation development, processing optimization, and regulatory compliance.