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Technical Data Sheet (TDS)

Product Name: OlanzapineCAS Number: 132539-06-1Product Number: OLA-20260220Revision Date: 20 FEB 2026

1. Product Overview

Olanzapine is a high-purity pharmaceutical raw material, a thienobenzodiazepine antipsychotic agent. It acts on multiple neurotransmitter receptors (5-HT, dopamine, muscarinic, adrenergic) to exert antipsychotic and mood-stabilizing effects. Produced in accordance with pharmaceutical GMP standards, it has high purity, low impurity content and stable quality, suitable for the production of oral solid preparations (tablets, capsules) and oral solutions.

Key Attributes:

- Formula: C_{17} H_{20} N_4S
- Molecular Weight: 312.43 g/mol
- Purity: ≥99.0% (HPLC)
- Form: White crystalline powder (odorless)

2. Technical Specifications (Pharmaceutical Grade)

Item	Specification
Appearance	White to off-white crystalline powder
Assay (HPLC)	≥99.0%
Melting Point	191-195℃
Loss on Drying	≤0.5%
Residue on Ignition	≤0.1%
Heavy Metals (Pb)	≤10 ppm
Related Substances (Individual)	≤0.1%
Related Substances (Total)	≤0.5%
Solubility	Freely soluble in methanol; slightly soluble in ethanol; insoluble in water
Particle Size	90% passing 100 mesh
Microbial Limit	Total Aerobic Microbial Count ≤100 CFU/g; Yeast & Mold ≤10 CFU/g; E. coli Negative

3. Product Advantages

1. **High Purity**: Pharmaceutical grade with assay ≥99.0%, low related substances, meeting USP/Ph. Eur./BP standards.
2. **Stable Quality**: Produced under GMP conditions, batch-to-batch consistency is excellent.
3. **Good Processability**: Uniform particle size, good flowability, suitable for direct compression and wet granulation.
4. **Comprehensive Certification**: Complies with international pharmaceutical standards, with DMF, COA provided for each batch.
5. **Strict Quality Control**: Full-process quality inspection from raw materials to finished products, ensuring no hazardous impurities.

4. Application Fields

- **Pharmaceutical Production**: Core raw material for antipsychotic drugs, used to produce olanzapine tablets, capsules, orally disintegrating tablets and oral solutions.
- **R&D Application**: Used in pharmaceutical research and development, biological experiments and clinical trial samples.

- **Scope of Use**: For the treatment of schizophrenia, bipolar disorder mania and mixed episodes (only for pharmaceutical manufacturing, not for direct use).

5. Usage & Processing Guidelines

- **Formulation Compatibility**: Compatible with common pharmaceutical excipients (lactose, microcrystalline cellulose, magnesium stearate, croscarmellose sodium).
- **Processing Conditions**: Process at 20-25℃, relative humidity ≤60%; avoid moisture and high temperature during granulation and tableting.
- **Dosage in Formulation**: Adjust according to the drug specification (common specifications: 2.5mg, 5mg, 10mg per tablet/capsule).
- **Mixing Requirement**: Mix evenly with excipients (mixing time ≥15 minutes) to ensure content uniformity.

6. Packaging & Storage

Packaging Specifications

- 1 kg/bag (aluminum foil vacuum bag, HDPE drum outer packing)
- 5 kg/drum (HDPE drum with aluminum foil inner lining, sealed)
- 10 kg/drum (HDPE drum with aluminum foil inner lining, sealed)
- Custom packaging (25 kg) available upon request (for large-scale production)

Storage Conditions

- **Temperature**: 2-8℃ (refrigerated storage)
- **Humidity**: Relative humidity ≤60%
- **Other**: Keep in a cool, dry, dark place; seal tightly to avoid light, moisture and air contact; store separately from strong acids, strong bases and oxidizing agents.

Shelf Life

- 24 months (unopened, stored in accordance with the above conditions); 6 months after opening (seal and refrigerate after each use).

Transportation

- Class 9 hazardous goods; transport with temperature-controlled insulated vehicles (2-8℃).
- Avoid direct sunlight, rain, collision and rough handling; comply with international transport regulations (IMDG/IATA/ADR).

7. Safety & Handling

- The product is a pharmaceutical raw material, **not for direct human/animal consumption**.
- Wear PPE (chemical splash goggles, nitrile gloves, lab coat, dust mask) during handling; avoid dust inhalation and eye/skin contact.
- Operate in a well-ventilated area; do not eat, drink or smoke in the handling area.
- In case of accidental contact (eye/skin) or ingestion, take first aid measures as specified in the MSDS and seek medical attention immediately.
- No open flame operation is required during handling (non-flammable).

8. Quality Assurance

1. Produced in accordance with **GMP** and ISO 9001 quality management system standards.
2. Each batch is accompanied by a **Certificate of Analysis (COA)** with full test results.
3. Provide **DMF (Drug Master File)**, MSDS and other technical documents as required by customers.
4. Accept third-party inspection (SGS, Intertek, CNAS) for product quality.
5. Provide professional technical support for formulation development and production process optimization.