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Technical Data Sheet (TDS)

Zaleplon CAS:151386-49-3 Version Date: 28 FEB 2026

1. Product Overview

- Product Name: Zaleplon (扎勒普隆)
- CAS Number: 151386-49-3
- Formula: $C_{17}H_{15}N_5O$
- Molecular Weight: 305.34 g/mol
- Chemical Classification: Non-benzodiazepine hypnotic (Z-drug class); pyrazolopyrimidine derivative
- Product Grade: Pharmaceutical Grade (EP/USP/CP Compliant)
- Product Characteristics: High-purity white crystalline powder; core API for short-acting hypnotic drugs; selective GABA-A receptor agonist; rapid onset of sleep (15-30 mins) and short duration of action; minimal next-day drowsiness; light-sensitive and slightly hygroscopic; 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 pale yellow 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
Melting Point	185-189℃	Capillary Melting Point Method
Solubility	Sparingly soluble in water, soluble in dimethyl sulfoxide	Pharmacopoeial Solubility Test
Chloride Content	≤ 0.01%	Volumetric Titration
Sulfate Content	≤ 0.03%	Volumetric Titration
Acidity/Alkalinity	pH 6.0-8.0 (0.1% in DMSO)	Digital pH Meter
Optical Rotation	0° ±1° (1% in DMSO)	Polarimetry
Particle Size	90% passing 100 mesh	Sieve Analysis

3. Product Advantages

1. **International Pharmacopoeial Compliance**: Meets EP/USP/CP global pharmaceutical standards; ultra-low related substances and heavy metal content; batch-to-batch consistency, suitable for GMP pharmaceutical formulation and commercial production of controlled drugs.
2. **Superior Hypnotic Activity**: Short-acting non-benzodiazepine hypnotic (Z-drug); selective GABA-A receptor agonist; rapid onset of sleep (15-30 minutes); short elimination half-life; minimal next-day residual effects (drowsiness, dizziness) – the gold standard for insomnia treatment with sleep onset difficulty.
3. **High Purity & Safety**: Pharmaceutical grade with ≥98.5% assay; strict control of toxic impurities and heavy metals; good clinical tolerability; low risk of dependence and withdrawal symptoms (compared with benzodiazepines); no significant acute toxicity at occupational exposure levels.
4. **Stable Quality Under Control**: 24-month shelf life at 2-8℃ dark storage; light-sensitive and slightly hygroscopic (controllable with light-proof, sealed packaging); no chemical degradation under standard pharmaceutical processing conditions.

5. **GMP Manufacturing**: Produced in GMP/ISO 9001 certified facility; complete raw material and production traceability; strict in-process quality control (IPC) compliant with controlled drug management regulations; meets international pharmaceutical quality standards.

4. Application Fields

- **Pharmaceutical Formulation**: Production of short-acting hypnotic drugs (tablets, capsules, oral disintegrating tablets) for clinical treatment of insomnia characterized by difficulty falling asleep.
- **Pharmaceutical R&D**: Research on new hypnotic formulations (sustained-release, sublingual); preclinical and clinical research on sleep disorders; drug combination research for comorbid insomnia and anxiety/depression; development of new non-benzodiazepine hypnotics.
- **Academic Research**: Neuroscience research on GABA-A receptor pharmacology and sleep regulation; research on the mechanism of hypnotic drug action; development of new pyrazolopyrimidine derivatives with hypnotic activity.

5. Usage & Formulation Guidelines

- **Formulation Compatibility**: Suitable for solid oral dosage forms (tablets, capsules, oral disintegrating tablets); compatible with common pharmaceutical excipients (microcrystalline cellulose, lactose, mannitol, magnesium stearate); soluble in DMSO/DMF for organic solvent-based formulations; solubilizers (e.g., cyclodextrins) required for aqueous formulations.
- **Typical Dosage (Formulated Drug)**: Adult oral dosage 5-10 mg before bedtime; maximum 20 mg/day – **clinical prescription only, controlled drug, no self-medication, no long-term continuous use**.
- **Processing Precautions**: Process in **light-free, dust-free, low-humidity (<60%) GMP workshop** (2-25℃); use closed, light-proof handling systems to avoid light exposure and dust generation; avoid contact with strong acids/bases, high temperature (>60℃) and open flame; maintain strict dust control to prevent respiratory sensitization.

6. Packaging & Storage

6.1 Packaging Specifications

- 100 g/bottle (amber glass bottle with aluminum foil light-proof/moisture-proof seal, inner plastic liner)
- 500 g/bottle (amber glass bottle with light-proof/moisture-proof seal)
- 1 kg/drum (opaque HDPE drum with inner light-proof plastic bag, sealed)
- 5 kg/drum (fiber drum with opaque HDPE inner liner, light-proof/moisture-proof)

6.2 Storage Conditions

- Store in a **cool, dry, dark warehouse at 2-8℃**; use light-proof, moisture-proof packaging; keep container tightly sealed to prevent light exposure, moisture absorption and dust contamination; avoid direct sunlight and high humidity (>60%).
- Incompatibilities: Store separately from strong acids, strong bases, oxidizing agents, food, feed and open flame sources.
- Shelf Life: **24 months** (unopened, under specified storage conditions); 6 months after opening (resealed, 2-8℃ dark storage).

6.3 Transportation

- Classified as UN 2811 (Class 6.1 Toxic Substance) + controlled pharmaceutical raw material; transport in **2-8℃ professional cold chain** with light-proof, sealed packaging.
- Mark with GHS hazard labels, UN 2811 and controlled drug signs; use temperature-monitored transport vehicles; avoid direct sunlight, high temperature, collision, vibration and open flame during transport.

7. Quality Assurance

- Manufactured in **GMP and ISO 9001 certified** production facility compliant with controlled drug management regulations; strict in-process quality control 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; complete production, quality and inventory records retained for 10 years (per controlled drug management requirements).