



NEWAY SINOPHC TECH. LIMITED

ADD:RM. 204, BUILDING 3, NO. 188, AONA RD., CHINA (SHANGHAI) PILOT FREE TRADE ZONE.
Email:marketing01@newayphc.com; Phone:+86-021-50350029 <https://www.newayphc.com>

Technical Data Sheet (TDS)

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1. Product Overview

Product Name: Triazolam English Name: Triazolam CAS Number: 2894-67-9 Formula: $C_{17}H_{12}ClN_5$ Molecular Weight: 343.77 g/mol Product Characteristics: Triazolam is a short-acting triazolobenzodiazepine sedative-hypnotic raw material, white crystalline powder, practically odorless, slightly hygroscopic and light-sensitive. It is practically insoluble in water, freely soluble in chloroform and ethanol. It has high affinity for brain GABA-A receptors, exerts sedative, hypnotic, anti-anxiety and muscle relaxant effects by potentiating GABA inhibitory neurotransmission. Rapid onset (15-30 minutes), short duration of action (2-4 hours), no obvious residual effect the next day. Stable under dry, dark and sealed storage conditions, suitable for preparing oral rapid-acting hypnotic formulations.

2. Technical Specifications (Complies with USP/EP/CP Industrial Standards)

Item	Specification
Appearance	White to off-white crystalline powder
Odor	Practically odorless
Assay (Triazolam)	$\geq 99.5\%$
Loss on Drying	$\leq 0.5\%$
Residue on Ignition	$\leq 0.1\%$
Heavy Metals (Pb)	≤ 2 ppm
Heavy Metals (As)	≤ 1 ppm
Related Substances	$\leq 0.3\%$
Sulfate (SO_4^{2-})	$\leq 0.02\%$
Melting Point	239-243°C
Total Bacterial Count	≤ 5 CFU/g
E. coli	Negative
Yeast & Mold	≤ 5 CFU/g
Particle Size	95% passing 100 mesh
Solubility in Chloroform	Freely soluble
Bulk Density	1.42-1.46 g/cm ³
Light Stability	$\leq 0.2\%$ related substances after 7 days (25°C, light exposure)

3. Product Advantages

- Ultra-Short Acting:** Rapid onset (15-30 minutes) and short duration of action (2-4 hours), no daytime drowsiness or cognitive impairment, ideal for insomnia with difficulty falling asleep.
- High Receptor Selectivity:** High affinity for central GABA-A receptors, strong sedative-hypnotic effect with low muscle relaxant and anticonvulsant activity, few adverse reactions.
- Pharmaceutical Grade Purity:** Assay $\geq 99.5\%$, related substances $\leq 0.3\%$, ultralow heavy metal and microbial limits, meets USP/EP/CP standards, suitable for oral pharmaceutical formulations.
- Good Formulation Compatibility:** Freely soluble in organic solvents (ethanol, chloroform), compatible with common oral excipients (lactose, starch, microcrystalline cellulose), easy to prepare tablets, capsules and oral solutions.
- Stable Storage:** 36-month shelf life under sealed, dark and dry conditions, slight hygroscopy with no significant impact on quality, easy to store and transport.

4. Application Fields

Oral Hypnotic Formulations: Core raw material for rapid-acting oral hypnotic tablets/capsules, used for the treatment of insomnia with difficulty falling asleep in adults, no obvious residual effect. Pharmaceutical R&D: Reference reagent for benzodiazepine receptor pharmacology, neuropharmacology and sedative-hypnotic drug research. Analytical Standard: Quality control reference material for the detection of benzodiazepine drugs in pharmaceutical and clinical laboratories.



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5. Usage & Formulation Guidelines

Recommended Formulation Concentration: Oral tablets (0.125 mg/tablet, 0.25 mg/tablet) - the main clinical dosage forms, with low dosage and high bioavailability. Formulation Process Tips: Mix triazolam with lactose, microcrystalline cellulose and starch in proportion, granulate with ethanol as wetting agent, dry under low temperature ($\leq 60^{\circ}\text{C}$, light protection), add magnesium stearate and compress into tablets; fill into hard gelatin capsules for capsule formulations. Key Notes: All formulation processes are carried out under **light protection** conditions; use ethanol as solvent to improve solubility; avoid high temperature and alkaline environment during production; the final formulation should be packaged in amber blister packs for light protection.

Compatible Excipients: Lactose, microcrystalline cellulose, corn starch, magnesium stearate, ethanol, hydroxypropyl methylcellulose (HPMC). Avoided Excipients: Strong acids, strong bases, oxidizing agents, alkaline excipients (sodium bicarbonate), benzodiazepine antagonists.

6. Packaging & Storage

Packaging Specifications: o 100 g/bottle: Amber glass pharmaceutical bottle with plastic inner cap + aluminum foil seal (laboratory/R&D use, light protection). o 1 kg/bag: Aluminum foil vacuum bag with PE inner lining (small-batch production use, light protection). o 5 kg/25 kg/drum: HDPE pharmaceutical-grade brown drum with aluminum foil inner lining + sealed plastic cover (bulk industrial production use, light protection). o Custom packaging available upon request (all with light protection). Storage Conditions: Store in a cool, dry, dark and locked pharmaceutical warehouse; temperature $\leq 25^{\circ}\text{C}$, relative humidity $\leq 60\%$; keep the container tightly sealed at all times to prevent hygroscopy and light degradation; store separately from strong acids, strong bases and oxidizing agents. Shelf Life: 36 months (unopened, under the specified storage conditions); 24 months for the prepared formulation (amber packaging, 25°C). Transportation: Class 6.1 toxic chemical transport; use sealed, light protection and shockproof containers; transport temperature $\leq 30^{\circ}\text{C}$; avoid direct sunlight, rain and collision; do not transport with food, feed and cosmetics.

7. Safety & Protection

The product is a toxic pharmaceutical intermediate with central nervous system depressant effects; all operations must be conducted by trained professional personnel with full PPE (N95 dust mask, full face shield, nitrile rubber gloves, impermeable lab coat). Operate in a well-ventilated dust-free fume hood under light protection conditions; avoid inhaling dust, skin and eye contact, and swallowing. Naloxone/flumazenil (benzodiazepine antagonist) must be available in the workplace for emergency use in case of accidental exposure. In case of eye contact: Rinse with plenty of water for at least 20 minutes and call a doctor immediately; in case of swallowing: Do not induce vomiting and call a poison center at once. Wash hands and exposed skin thoroughly with soap and water after handling; take a shower if necessary.

8. Quality Assurance

The product is manufactured in accordance with **GMP (Good Manufacturing Practice)** for pharmaceutical intermediates and ISO 9001 quality management system; full-process light protection, dust-free and closed production, with complete traceability of production and inspection records. Each batch undergoes full-item testing (HPLC/AAS/melting point apparatus, etc.) in the professional light protection quality inspection center; a detailed English COA is provided with each shipment, including all key quality indexes. Accept third-party testing by international institutions (SGS/Intertek/CNAS) with light protection testing conditions; provide free testing samples upon customer request. Professional technical support team provides one-stop formulation design, production process optimization and quality control guidance; 24-hour online technical consultation. Perfect after-sales service: quality feedback processing within 48 hours; product replacement/refund for unqualified batches in accordance with COA standards; provide all export documents (COA/MSDS/packing list/toxic chemical transport approval).