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)

Nitrazepam CAS:146-22-5Version Date: 28 FEB 2026

1. Product Overview

- Product Name: Nitrazepam (硝西泮)
- CAS Number: 146-22-5
- Formula: $C_{15}H_{11}N_3O_3$
- Molecular Weight: 281.27 g/mol
- Chemical Classification: Benzodiazepine derivative
- Product Grade: Pharmaceutical Grade (EP/USP/CP Compliant)
- Product Characteristics: Pale yellow high-purity crystalline powder; classic benzodiazepine API for sedative/hypnotic/anti-anxiety drugs; light-sensitive; sparingly soluble in ethanol, insoluble in water; potent CNS depressant activity; strict impurity control for pharmaceutical use.

2. Technical Specifications (EP 10.0 / USP 45 / CP 2020)

Item	Specification	Test Method
Appearance	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)	≤ 10 ppm	Atomic Absorption Spectrometry (AAS)
Heavy Metals (As)	≤ 2 ppm	Atomic Fluorescence Spectrometry (AFS)
Related Substances	Each impurity ≤ 0.5%; Total ≤ 1.0%	HPLC
Melting Point	226-231℃	Capillary Melting Point Method
Solubility	Sparingly soluble in ethanol, practically insoluble in water	Pharmacopoeial Solubility Test
Chloride Content	≤ 0.01%	Volumetric Titration
Sulfate Content	≤ 0.03%	Volumetric Titration
Acidity/Alkalinity	pH 6.0-8.0 (0.5% in ethanol)	Digital pH Meter
Particle Size	90% passing 100 mesh	Sieve Analysis

3. Product Advantages

1. **International Pharmacopoeial Compliance**: Meets EP/USP/CP standards; low related substances/heavy metals; batch-to-batch consistency, suitable for GMP pharmaceutical formulation and controlled drug production.
2. **Potent Benzodiazepine Activity**: Classic sedative/hypnotic/anti-anxiety API; rapid onset of hypnotic effect; long duration of action; effective for insomnia, anxiety and mild convulsions (clinical use).
3. **Stable Quality Under Control**: 24-month shelf life at 2-8℃ dark storage; light-sensitive but stable with sealed/opaque packaging; no significant degradation under pharmaceutical processing conditions.
4. **Formulation Flexibility**: Sparingly soluble in ethanol, compatible with organic solvent-based formulations; suitable for solid oral dosage forms (tablets/capsules) and sublingual formulations.
5. **GMP Manufacturing**: Produced in GMP/ISO 9001 certified facility; complete raw material traceability; strict in-process quality control (compliant with controlled drug management regulations).

4. Application Fields

- **Pharmaceutical Formulation**: Production of sedative/hypnotic/anti-anxiety drugs (tablets, capsules, sublingual tablets) for clinical treatment of insomnia, generalized anxiety disorder and mild convulsive disorders.
- **Pharmaceutical R&D**: Research on new benzodiazepine formulations (sustained-release, low-side-effect); preclinical/clinical research on CNS disorders; drug-drug interaction studies of benzodiazepines.
- **Academic Research**: Neuroscience research on GABA-A receptor pharmacology; sleep disorder pathogenesis research; benzodiazepine structure-activity relationship studies.

5. Usage & Formulation Guidelines

- **Formulation Compatibility**: Suitable for solid oral dosage forms (tablets/capsules); compatible with common excipients (lactose, microcrystalline cellulose, magnesium stearate); solubilizers (e.g., PEG 400) required for aqueous formulations.
- **Typical Dosage (Formulated Drug)**: Adult oral dosage 5-10 mg before bedtime (hypnotic); 2.5-5 mg tid (anti-anxiety) – **clinical prescription only, controlled drug, no self-medication**.
- **Processing Precautions**: Process in **light-free, dust-free GMP workshop** (2-25℃); use closed/opaque handling systems to avoid light exposure and dust generation; avoid contact with strong acids/bases/high temperature (>25℃).

6. Packaging & Storage

6.1 Packaging Specifications

- 100 g/bottle (amber glass bottle with aluminum foil seal, inner plastic liner – light-proof)
- 500 g/bottle (amber glass bottle with light-proof seal)
- 1 kg/drum (opaque HDPE drum with inner plastic bag, sealed)
- 5 kg/drum (fiber drum with opaque HDPE inner liner, light-proof)
- Custom GMP-compliant/light-proof packaging for industrial bulk orders (controlled drug regulations apply)

6.2 Storage Conditions

- Store in a **cool, dry, dark warehouse at 2-8℃**; use light-proof packaging; keep container tightly sealed to prevent light exposure and moisture.
- Avoid direct sunlight, high temperature (>25℃), strong acids, strong bases and oxidizing agents.
- Shelf Life: **24 months** (unopened, specified conditions); 6 months after opening (resealed, 2-8℃ dark storage).
- Segregation: Store as a **controlled pharmaceutical raw material**; separate from food/feed/non-pharmaceutical materials; keep in locked storage area with authorized personnel only.

6.3 Transportation

- Classified as UN 2811 (Class 6.1 Toxic Substance) + controlled drug; transport with **2-8℃ cold chain** and light-proof packaging.
- Mark with GHS hazard labels, UN 2811 and controlled drug signs; avoid direct sunlight, high temperature and collision during transport.
- Comply with IMDG/IATA/ADR for Class 6.1 toxic solids (cold chain) and local controlled drug transport regulations; do not transport with food/feed/strong acids/bases.

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 key parameters.
- Each batch is accompanied by a batch-specific **Certificate of Analysis (COA)** with full test results; complete production/quality records retained for 5+ years (per controlled drug regulations).
- Professional technical support for pharmaceutical formulation development; compliance guidance for controlled drug manufacturing/handling/storage.