纳维盈医化科技
NEWAY SINOPHC TECH

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)

1. Product Overview

- **Product Name**: Sulfadoxine (磺胺多辛)
- **CAS Number**: 2447-57-6
- **Formula**: $C_{12}H_{14}N_4O_2S$
- **Formula Weight**: 278.33 g/mol
- **Product Characteristics**: High-purity synthetic sulfonamide antibacterial/antimalarial pharmaceutical raw material, a long-acting sulfonamide derivative with potent activity against gram-positive/gram-negative bacteria and *Plasmodium falciparum*. White to off-white crystalline powder, almost odorless, sparingly soluble in organic solvents, soluble in dilute acids/alkalis, stable under recommended storage conditions. Pharmaceutical grade meets CP/USP/EP standards, core raw material for oral antibacterial/antimalarial combination drugs (e.g., sulfadoxine-pyrimethamine), with long half-life and sustained therapeutic effect.

2. Technical Specifications (CP/USP/EP Compliant)

Item	Specification (Pharmaceutical Grade)
Appearance	White to off-white crystalline powder, almost odorless
Assay (Purity, on dry basis)	≥ 99.0% (HPLC)
Loss on Drying	≤ 0.5% (105℃, 2h)
Residue on Ignition	≤ 0.1% (600℃±50℃)
Heavy Metals (Pb)	≤ 5 ppm
Heavy Metals (As)	≤ 1 ppm
Melting Point	195-200℃
pH Value (1% suspension, 25℃)	5.5-7.5
Related Substances	≤ 0.5% (HPLC)
Residual Solvents	Meets USP <467> limits
Microbial Limit	Total Aerobic Count ≤100 CFU/g; Yeast/Mold ≤10 CFU/g
Pathogens	E. coli, Salmonella, Staphylococcus aureus: Negative
Solubility	Sparingly soluble in acetone; soluble in dilute acids/alkalis
Particle Size	100-200 mesh (standard); customizable 80-300 mesh
Temperature Stability	Stable at 0-30℃ (purity retention ≥99%)
Light Stability	Stable in dark; slight degradation under strong UV light

3. Product Advantages

1. **High Purity & Pharmacopoeia Compliance**: ≥99.0% assay, meets CP/USP/EP international standards, low impurity/heavy metal content, consistent batch quality.
2. **Long-Acting Pharmacokinetic Profile**: Long plasma half-life (≈140h), sustained therapeutic concentration, reduces medication frequency (once weekly for malaria prophylaxis).
3. **Broad-Spectrum Activity**: Effective against gram-positive/gram-negative bacteria and malarial plasmodia, suitable for combination anti-infective/antimalarial therapy.
4. **Excellent Stability**: 36-month shelf life under cool/dry conditions, no significant degradation during storage/transport; stable in formulated dosage forms.
5. **Pharmaceutical Compatibility**: Reacts with dilute acids/alkalis to form soluble salts, easy for formulation of oral dosage forms (tablets, capsules, suspensions).
6. **Well-Characterized Profile**: Comprehensive toxicological and pharmacological data, safe for clinical use at therapeutic dosages (excluding sulfonamide-allergic individuals).

4. Application Fields

- **Pharmaceutical Industry**: Production of oral sulfadoxine-pyrimethamine combination tablets (antimalarial); synthesis of long-acting antibacterial drugs for respiratory/urinary tract infections.
- **Biomedical Research**: Research reagent for studying sulfonamide drug mechanisms; antibacterial/antimalarial drug resistance research.

- **Veterinary Medicine**: Synthesis of long-acting veterinary antibacterial drugs for livestock/poultry bacterial infections (excluding food-producing animals in some regions).

5. Usage Methods

- **Pharmaceutical Formulation**: Used as active pharmaceutical ingredient (API); form into combination tablets (sulfadoxine 500mg + pyrimethamine 25mg per unit) with excipients (lactose, starch, magnesium stearate); prepare into oral suspensions for paediatric use (after acid solubilization).
- **Research Use**: 0.01-10 mM concentration for in vitro cell/bacterial experiments; dissolve in DMSO/dilute NaOH solution to prepare stock solution (store at 2-8℃).
- **Critical Notes**:

1. Raw powder **not for direct use**; must be formulated with pharmaceutical excipients and processed under GMP conditions.
2. Avoid use in sulfonamide-allergic individuals; strict dosage control required to avoid hematological side effects.
3. Formulated products must be marked with sulfonamide allergy hazard warning.

6. Packaging & Storage

Packaging Specifications

- 100 g/bottle (pharmaceutical grade, amber glass bottle with PE liner, sealed)
- 1 kg/tin (pharmaceutical/industrial grade, sealed tin can with PE liner)
- 5 kg/drum (industrial grade, HDPE drum with airtight seal)
- 25 kg/drum (bulk industrial grade, paper drum with aluminum foil liner)
- Custom packaging (10g/50g) for research/small-batch orders (sealed vials)

Storage Conditions

- Store in a **cool, dry, dark** warehouse with temperature ≤25℃ and relative humidity ≤60%.
- Keep container **airtight and sealed** to prevent moisture absorption and light degradation.
- Store separately from strong acids, oxidizing agents, heavy metal salts, food and feed raw materials.
- Avoid high temperature (>30℃) and repeated freeze-thaw cycles.
- Segregate from other pharmaceutical APIs for sulfonamide-allergic use (per hazardous chemical storage regulations).

Shelf Life

- 36 months (unopened, pharmaceutical grade, under specified storage conditions)
- 24 months (unopened, industrial grade, under specified storage conditions)
- 6 months after opening (if sealed and stored properly at 2-8℃ for research use)
- Comply with international hazardous chemical transport regulations (ADR/RID/IMDG/IATA).

7. Safety & Protection

- The product is **harmful if swallowed**, causes skin/serious eye irritation and may trigger allergic skin reactions in sulfonamide-sensitive individuals.
- **Mandatory PPE** for handling: chemical safety goggles, N95/P95 dust mask, nitrile rubber gloves (≥0.18mm), impermeable protective clothing.
- Operate in a well-ventilated fume hood/area; avoid dust generation and inhalation; identify sulfonamide-allergic personnel before operation.
- Do not eat/drink/smoke in the work area; wash hands/face thoroughly with soap and water after handling.

8. Quality Assurance

- Manufactured in accordance with **GMP (Good Manufacturing Practice)**, **ISO 9001 (Quality)** and **ISO 14001 (Environment)** standards.
- Each batch is tested by an independent third-party laboratory and accompanied by a **Certificate of Analysis (COA)**.
- Provide **pharmacopoeial compliance documents** (CP/USP/EP) and hazardous chemical safety certificates for pharmaceutical grade products.
- Standardized synthesis and purification process, low batch-to-batch variation, stable product quality.