纳维盈医化科技
NEWAY SINOPHC TECH

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Technical Data Sheet (TDS)

1. Product Overview

- **Product Name**: Pyrimethamine (乙胺嘧啶)
- **CAS Number**: 58-14-0
- **Formula**: $C_{12}H_{13}ClN_4$
- **Formula Weight**: 248.71 g/mol
- **Product Characteristics**: High-purity synthetic anti-malarial/anti-parasitic pharmaceutical raw material, a dihydrofolate reductase inhibitor with long-acting anti-plasmodial activity. White crystalline powder, almost odorless, sparingly soluble in organic solvents, insoluble in water, stable under recommended storage conditions. Pharmaceutical grade meets CP/USP/EP standards, core raw material for anti-malarial combination drugs and veterinary anti-parasitic formulations, with potent activity against Plasmodium falciparum and Toxoplasma gondii.

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

Item	Specification (Pharmaceutical Grade)
Appearance	White to creamy white crystalline powder, almost odorless
Assay (Purity)	≥ 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	237-242℃
Related Substances	≤ 0.8% (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 ethanol (1g/200mL); insoluble in water
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 & Quality**: ≥99.0% assay, meets international pharmacopoeial standards, low impurity/heavy metal content, consistent batch quality
2. **Potent Anti-Parasitic Activity**: Long-acting dihydrofolate reductase inhibitor, high activity against Plasmodium and Toxoplasma, core raw material for anti-malarial combination therapies
3. **Good Stability**: 24-month shelf life under cool/dry conditions, no significant degradation during storage/transport
4. **Pharmaceutical Compatibility**: Reacts with dilute acids to form soluble salts, easy for pharmaceutical formulation (tablets, capsules, suspensions)
5. **Controlled Toxicity**: Well-characterized toxicological profile, safe for clinical/veterinary use when formulated at therapeutic dosages
6. **Customizable**: Custom particle size available for different formulation processes (direct compression, wet granulation)

4. Application Fields

- **Pharmaceutical Industry**: Production of anti-malarial combination drugs; oral anti-toxoplasmosis drugs for human clinical use
- **Veterinary Medicine**: Synthesis of veterinary anti-parasitic drugs for livestock/poultry (anti-coccidiosis, anti-malaria)
- **Biomedical Research**: Research reagent for studying anti-malarial drug mechanisms; dihydrofolate reductase inhibitor in cell biology experiments

- **Fine Chemicals**: Intermediate for synthesis of novel anti-parasitic and anti-cancer drugs with folate pathway inhibition activity

5. Usage Methods

- **Pharmaceutical Formulation**: Used as active pharmaceutical ingredient (API); form into tablets/capsules (25-50mg per unit) with excipients (lactose, starch, magnesium stearate); can be prepared into oral suspensions for paediatric use (after acid solubilization)
- **Veterinary Formulation**: 50-200 mg/kg body weight (formulated with feed additives); prepare into oral powder for livestock/poultry
- **Research Use**: 0.01-1 mM concentration for in vitro cell experiments; dissolve in DMSO/dilute HCl to prepare stock solution
- **Note**: Raw powder **not for direct use**; must be formulated with pharmaceutical excipients and processed under GMP conditions; strict dosage control required

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, alkaline solutions, food and feed raw materials
- Avoid high temperature (>30℃) and repeated freeze-thaw cycles
- Segregate from other pharmaceutical APIs for human use (per hazardous chemical storage regulations)

Shelf Life

- 24 months (unopened, pharmaceutical grade, specified storage conditions)
- 18 months (unopened, industrial grade, specified storage conditions)
- 6 months after opening (if sealed and stored properly at 2-8℃ for research use)

7. Safety & Protection

- The product is **harmful if swallowed** and causes serious eye irritation; suspected genotoxicity
- **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
- Do not eat/drink/smoke in the work area; wash hands/face thoroughly with soap and water after handling
- In case of eye contact, **immediately rinse with plenty of water for 15-20 mins and consult a doctor**
- In case of ingestion, **do not induce vomiting and immediately call a poison control center/doctor**
- Non-combustible; wear SCBA and full fire-fighting gear in case of fire (avoid decomposition fumes)

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