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**: Mefloquine (甲氟喹)
- **CAS Number**: 59635-93-3
- **Formula**: $C_{17}H_{16}F_6N_2O$
- **Formula Weight**: 378.32 g/mol
- **Product Characteristics**: High-purity synthetic 4-quinolinemethanol anti-malarial pharmaceutical raw material, with potent activity against *Plasmodium falciparum* (including chloroquine-resistant strains) and *Plasmodium vivax*. 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 oral anti-malarial drugs (prophylaxis and treatment of malaria) and veterinary anti-parasitic formulations, with long-acting anti-plasmodial effects.

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)	≥ 98.5% (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	250-255℃ (decomposition)
Related Substances	≤ 1.0% (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/180mL); 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 & Pharmacopoeia Compliance**: ≥98.5% assay, meets CP/USP/EP international standards, low impurity/heavy metal content, consistent batch quality.
2. **Broad-Spectrum Anti-Malarial Activity**: Effective against chloroquine-resistant *Plasmodium falciparum*, suitable for malaria treatment in drug-resistant areas; also effective for malaria prophylaxis.
3. **Long-Acting Effect**: Sustained blood concentration, long anti-malarial duration, reduces medication frequency.
4. **Good Stability**: 24-month shelf life under cool/dry conditions, no significant degradation during storage/transport.
5. **Pharmaceutical Compatibility**: Reacts with organic acids 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.

4. Application Fields

- **Pharmaceutical Industry**: Production of oral anti-malarial drugs for prophylaxis and treatment of malaria; raw material for anti-malarial combination drugs.
- **Veterinary Medicine**: Synthesis of veterinary anti-parasitic drugs for livestock/poultry (anti-malaria, anti-babesiosis) in endemic areas.

- **Biomedical Research**: Research reagent for studying anti-malarial drug mechanisms; drug resistance research of plasmodium.
- **Public Health**: Raw material for malaria prevention programs in travel medicine and malaria-endemic regions.

5. Usage Methods

- **Pharmaceutical Formulation**: Used as active pharmaceutical ingredient (API); form into tablets/capsules (250-500mg per unit) with excipients (lactose, starch, magnesium stearate); can be prepared into oral suspensions for paediatric use (after acid solubilization).
- **Veterinary Formulation**: 5-10 mg/kg body weight (formulated with feed additives); prepare into oral powder for livestock/poultry in malaria-endemic areas.
- **Research Use**: 0.01-1 mM concentration for in vitro cell experiments; dissolve in DMSO/dilute organic acid 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 (avoid neurological/psychiatric side effects).

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, under specified storage conditions)
- 18 months (unopened, industrial grade, under 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 skin/serious eye irritation; may cause neurological/respiratory irritation at high exposure.
- **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.

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.