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**: Chloroquine Phosphate (磷酸氯喹)
- **CAS Number**: 50-63-5
- **Formula**: $C_{18}H_{26}ClN_3 \cdot 2H_3PO_4$
- **Formula Weight**: 515.87 g/mol
- **Product Characteristics**: High-purity synthetic anti-malarial pharmaceutical raw material, a 4-aminoquinoline derivative with potent anti-plasmodial activity and anti-inflammatory/immunomodulatory effects. White to off-white crystalline powder, freely soluble in water (a key advantage over chloroquine base), stable under recommended storage conditions. Pharmaceutical grade meets CP/USP/EP standards, core raw material for oral/parenteral anti-malarial drugs, and used in research for anti-inflammatory and anti-viral studies.

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	≤ 2.0% (105℃, 2h)
Residue on Ignition	≤ 0.1% (600℃±50℃)
Heavy Metals (Pb)	≤ 5 ppm
Heavy Metals (As)	≤ 1 ppm
pH Value (1% aqueous solution, 25℃)	3.5-4.5
Melting Point	215-220℃ (decomposition)
Chloride Content	6.5-7.0% (titration)
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	Freely soluble in water (1g/1.5mL); slightly soluble in ethanol
Particle Size	100-200 mesh (standard); customizable 80-300 mesh
Temperature Stability	Stable at 0-30℃ (purity retention ≥98%)
Light Stability	Stable in dark; slight degradation under strong UV light

3. Product Advantages

1. **High Purity & Quality**: ≥98.5% assay (on dry basis), meets international pharmacopoeial standards, low impurity/heavy metal content, consistent batch quality
2. **Excellent Water Solubility**: Freely soluble in water (unlike chloroquine base), ideal for oral and injectable pharmaceutical formulations
3. **Potent Biological Activity**: Broad-spectrum anti-malarial activity against Plasmodium falciparum/vivax; anti-inflammatory and immunomodulatory effects for research use
4. **Good Stability**: 24-month shelf life under cool/dry conditions, no significant degradation during storage/transport; stable in aqueous solutions (short-term)
5. **Pharmaceutical Compatibility**: Easy to formulate into various dosage forms (tablets, capsules, injections, syrups) with common pharmaceutical excipients
6. **Well-Characterized**: Comprehensive toxicological and pharmacological profile, safe for clinical/veterinary use when formulated at therapeutic dosages

4. Application Fields

- **Pharmaceutical Industry**: Production of oral/parenteral anti-malarial drugs; raw material for formulations treating malaria and amoebic liver abscess
- **Biomedical Research**: Research reagent for anti-inflammatory, anti-viral and immunomodulatory mechanism studies; 4-aminoquinoline derivative for drug discovery

- **Veterinary Medicine**: Synthesis of veterinary anti-malarial/anti-parasitic drugs for livestock/poultry and exotic animals
- **Fine Chemicals**: Intermediate for synthesis of novel 4-aminoquinoline derivatives with enhanced anti-malarial/anti-cancer activity

5. Usage Methods

- **Pharmaceutical Formulation**: Used as active pharmaceutical ingredient (API); form into oral tablets/capsules (100-250mg per unit) with excipients (lactose, starch, PVP); prepare into injectable solutions (50mg/mL) with water for injection (pH adjusted to 3.5-4.5)
- **Paediatric Formulation**: Prepare into oral syrups (50mg/5mL) with sweeteners and preservatives (sucrose, methylparaben)
- **Research Use**: 0.01-5 mM concentration for in vitro cell experiments; dissolve directly in water to prepare stock solution (no organic solvent required)
- **Note**: Raw powder **not for direct use**; must be formulated with pharmaceutical excipients and processed under GMP conditions; strict dosage control required for clinical use

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 bases, oxidizing agents, alkaline carbonates and food/feed raw materials
- Avoid high temperature (>30℃) and repeated freeze-thaw cycles; aqueous formulations stored at 2-8℃ (7-day shelf life)
- 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 skin/serious eye irritation; prolonged exposure may cause eye damage
- **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**

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