

Technical Data Sheet (TDS)

1. Product Overview

- **Product Name:** Piperaquine Phosphate (磷酸哌喹)
- **CAS Number:** 85547-56-4
- **Formula:** $C_{29}H_{32}Cl_2N_6 \cdot 4H_3PO_4$
- **Formula Weight:** 810.56 g/mol
- **Product Characteristics:** High-purity synthetic 4-aminoquinoline anti-malarial pharmaceutical raw material, core ingredient of **artemisinin-based combination therapies (ACTs)** recommended by WHO for the treatment of uncomplicated malaria. White to pale yellow crystalline powder, freely soluble in water (a key advantage for formulation), stable under recommended storage conditions, almost odorless. Pharmaceutical grade meets CP/USP/EP/WHO standards, with potent and long-acting anti-plasmodial activity against *Plasmodium falciparum* and *Plasmodium vivax*; widely used in malaria control and elimination programs worldwide.

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

Item	Specification (Pharmaceutical Grade)
Appearance	White to pale yellow crystalline powder, almost odorless
Assay (Purity, on dry basis)	≥ 98.0% (HPLC)
Loss on Drying	≤ 2.0% (105°C, 2h)
Residue on Ignition	≤ 0.1% (600°C±50°C)
Heavy Metals (Pb)	≤ 5 ppm
Heavy Metals (As)	≤ 1 ppm
pH Value (1% aqueous solution, 25°C)	3.5-4.5
Melting Point	235-240°C (decomposition)
Phosphate Content	38.0-40.0% (titration)
Related Substances	≤ 1.5% (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	Freely soluble in water (1g/1.8mL); slightly soluble in ethanol
Particle Size	100-200 mesh (standard); customizable 80-300 mesh
Temperature Stability	Stable at 0-30°C (purity retention ≥98%)
Light Stability	Stable in dark; slight degradation under strong UV light

3. Product Advantages

1. **WHO Recommended API:** Core ingredient of artemisinin-based combination therapies (ACTs), the first-line treatment for malaria recommended by WHO.
2. **Excellent Water Solubility:** Freely soluble in water, ideal for oral and injectable pharmaceutical formulations (no organic solvent required for dissolution).
3. **Long-Acting Anti-Malarial Activity:** Sustained anti-plasmodial effect, low recurrence rate, perfect for combination with short-acting artemisinin derivatives.
4. **High Purity & Compliance:** ≥98.0% assay, meets CP/USP/EP/WHO international standards, low impurity/heavy metal content, consistent batch quality.
5. **Good Stability:** 24-month shelf life under cool/dry conditions, no significant degradation during storage/transport; stable in aqueous solutions (short-term).

6. **Broad-Spectrum Activity:** Effective against both *Plasmodium falciparum* and *Plasmodium vivax*, suitable for malaria treatment in global endemic areas.

4. Application Fields

- **Pharmaceutical Industry:** Production of artemisinin-piperaquine combination tablets/capsules (first-line anti-malarial drugs); raw material for other anti-malarial combination formulations.
- **Public Health:** Core raw material for global malaria control and elimination programs; used in malaria treatment in endemic areas by WHO and national health departments.
- **Biomedical Research:** Research reagent for studying anti-malarial drug mechanisms; combination drug research of artemisinin derivatives and quinoline anti-malarials.
- **Veterinary Medicine:** Synthesis of veterinary anti-malarial/anti-parasitic drugs for livestock/poultry and exotic animals in malaria-endemic regions.

5. Usage Methods

- **Pharmaceutical Formulation:** Used as active pharmaceutical ingredient (API); form into artemisinin-piperaquine combination tablets (piperaquine 320mg + artemisinin 60mg per unit) with excipients (lactose, starch, PVP); prepare into oral suspensions for paediatric use (dissolved in water with sweeteners).
- **Research Use:** 0.01-5 mM concentration for in vitro cell experiments; dissolve directly in water to prepare stock solution (store at 2-8°C, valid for 7 days).
- **Note:** Raw powder **not for direct use**; must be formulated with pharmaceutical excipients and processed under GMP conditions; only used in combination with artemisinin derivatives for clinical malaria treatment (per WHO guidelines).

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 $\leq 25^{\circ}\text{C}$ and relative humidity $\leq 60\%$.
- 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 ($>30^{\circ}\text{C}$) and repeated freeze-thaw cycles; aqueous formulations stored at 2-8°C (7-day shelf life).
- Segregate from other pharmaceutical APIs (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°C for research use)