

Technical Data Sheet (TDS)

1. Product Overview

- **Product Name:** Primaquine Phosphate (磷酸伯氨喹)
- **CAS Number:** 150-99-2
- **Formula:** C₁₅ H₂₁N₃O · 2H₃PO₄
- **Formula Weight:** 455.34 g/mol
- **Product Characteristics:** High-purity synthetic 8-aminoquinoline derivative, core anti-malarial pharmaceutical raw material for the **radical cure of malaria** (kills hypnozoites of *Plasmodium vivax* and *Plasmodium ovale* in the liver). Orange-red crystalline powder, freely soluble in water, light-sensitive and stable under cool/dark conditions, with a bitter taste. Pharmaceutical grade meets CP/USP/EP/WHO standards, a first-line anti-malarial drug for preventing malaria recurrence; critical note: causes hemolysis in G6PD-deficient individuals. Core raw material for oral anti-malarial drugs and veterinary anti-parasitic formulations.

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

| Item | Specification (Pharmaceutical Grade) |
|--------------------------------------|--|
| Appearance | Orange-red to red 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 |
| Melting Point | 200-205°C (decomposition) |
| pH Value (1% aqueous solution, 25°C) | 4.0-5.0 |
| Phosphate Content | 34.0-36.0% (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/1.2mL); slightly soluble in ethanol |
| Particle Size | 100-200 mesh (standard); customizable 80-300 mesh |
| Temperature Stability | Stable at 0-25°C (purity retention ≥97%) |
| Light Stability | Stable in dark; degrades under strong UV light (purity loss ≥5%/72h) |

3. Product Advantages

1. **First-Line Anti-Malarial for Radical Cure:** Unique activity against malaria hypnozoites in the liver, prevents malaria recurrence (no substitute for other anti-malarial drugs).
2. **Pharmacopoeia & WHO Compliance:** ≥98.0% assay, meets CP/USP/EP/WHO international standards, low impurity/heavy metal content, consistent batch quality.
3. **Good Water Solubility:** Freely soluble in water, suitable for oral liquid, tablets and other pharmaceutical formulations (easy for clinical use).
4. **Controlled Toxicity Profile:** Well-characterized toxicological profile, safe for clinical use at therapeutic dosages (excluding G6PD-deficient individuals).
5. **Light-Proof Packaging:** Factory-supplied amber glass packaging, effectively preventing light-induced degradation during storage/transport.
6. **Pharmaceutical Compatibility:** Easy to formulate with common pharmaceutical excipients (lactose, starch, PVP) for various oral dosage forms.

4. Application Fields



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- **Pharmaceutical Industry:** Production of oral anti-malarial drugs for the radical cure of *Plasmodium vivax* and *Plasmodium ovale* malaria; WHO essential medicine for malaria control programs.
- **Veterinary Medicine:** Synthesis of veterinary anti-parasitic drugs for livestock/poultry (anti-malaria, anti-babesiosis); radical cure of animal malaria.
- **Biomedical Research:** Research reagent for studying anti-malarial drug mechanisms; 8-aminoquinoline derivative model in pharmacology/hematology experiments.
- **Public Health:** Raw material for malaria elimination programs in endemic areas (prevention of malaria recurrence and transmission).

5. Usage Methods

- **Pharmaceutical Formulation:** Used as active pharmaceutical ingredient (API); formulate into tablets (15mg base per unit) with excipients (lactose, starch, magnesium stearate); prepare into oral liquid (5mg base/5mL) for paediatric use (dissolved in water with sweeteners).
- **Veterinary Formulation:** 2-5 mg/kg body weight (based on primaquine base); formulate into oral powder/injectable solution for livestock/poultry (avoid use in G6PD-deficient animals).
- **Research Use:** 0.001-1 mM concentration for in vitro cell experiments; dissolve directly in water to prepare stock solution (store in dark at 2-8°C, valid for 7 days).
- **Critical Notes:**
 1. Raw powder **not for direct use**; must be formulated under GMP conditions with strict dosage control.
 2. Avoid use in G6PD-deficient individuals/animals (risk of severe hemolysis).
 3. Formulated products must be marked with G6PD deficiency hazard warning.

6. Packaging & Storage

Packaging Specifications

- 50 g/bottle (pharmaceutical grade, amber glass bottle with PE liner, airtight sealed)
- 1 kg/tin (pharmaceutical/industrial grade, sealed light-proof tin can with PE liner)
- 5 kg/drum (industrial grade, light-proof HDPE drum with airtight seal)
- 25 kg/drum (bulk industrial grade, paper drum with aluminum foil + black plastic liner)
- Custom packaging (10g/20g) for research/small-batch orders (amber glass vials, sealed)

Storage Conditions

- Store in a **cool, dry, dark** warehouse with temperature $\leq 20^{\circ}\text{C}$ and relative humidity $\leq 50\%$.
- Keep container **airtight and sealed** (light-proof packaging unopened) to prevent light/moisture-induced degradation.
- Store separately from strong bases, oxidizing agents, reducing agents, food and feed raw materials.
- Avoid high temperature ($>25^{\circ}\text{C}$) and repeated freeze-thaw cycles; formulated products stored at 2-8°C (dark condition).
- Segregate from other pharmaceutical APIs; mark clearly with **G6PD deficiency hazard warning** and GHS toxic labels.

Shelf Life

- 24 months (unopened, pharmaceutical grade, under specified storage conditions)
- 18 months (unopened, industrial grade, under specified storage conditions)
- 3 months after opening (if sealed, dark and stored at 2-8°C for research use)

Transportation

- **Hazardous Class 6.1 (Toxic substance), Packaging Group II:** Transport by licensed hazardous chemical cargo vehicles (refrigerated transport at $\leq 20^{\circ}\text{C}$).
- Use light-proof packaging; avoid direct sunlight, rain, moisture, collision and breakage of containers during transport.