

## Technical Data Sheet (TDS)

### 1. Product Overview

- **Product Name:** Quinine Dihydrochloride (奎宁二盐酸盐)
- **CAS Number:** 60-93-5
- **Formula:**  $C_{20}H_{24}N_2O_2 \cdot 2HCl$
- **Formula Weight:** 397.34 g/mol
- **Product Characteristics:** High-purity natural alkaloid derivative (extracted from Cinchona bark), core anti-malarial pharmaceutical raw material with potent anti-plasmodial activity against *Plasmodium falciparum* and *Plasmodium vivax*. White crystalline powder, freely soluble in water (a key advantage over quinine base), stable under recommended storage conditions, with bitter taste and slight anti-inflammatory/analgesic effects. Pharmaceutical grade meets CP/USP/EP standards, core raw material for oral/parenteral anti-malarial drugs and veterinary anti-parasitic formulations.

### 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	≤ 1.0% (105°C, 2h)
Residue on Ignition	≤ 0.1% (600°C±50°C)
Heavy Metals (Pb)	≤ 5 ppm
Heavy Metals (As)	≤ 1 ppm
Melting Point	235-240°C (decomposition)
pH Value (5% aqueous solution, 25°C)	2.0-3.0
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/0.8mL); 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. **High Purity & Pharmacopoeia Compliance:** ≥98.5% assay, meets CP/USP/EP international standards, low impurity/heavy metal content, consistent batch quality.
2. **Excellent Water Solubility:** Freely soluble in water, suitable for oral liquid, injection and other pharmaceutical formulations (unlike quinine base with poor water solubility).
3. **Potent Anti-Malarial Activity:** Natural alkaloid with broad-spectrum anti-plasmodial activity, effective for treating uncomplicated malaria and cerebral malaria.
4. **Good Stability:** 24-month shelf life under cool/dry conditions, no significant degradation during storage/transport; stable in aqueous solutions (short-term).
5. **Multi-Functional Activity:** With slight anti-inflammatory, analgesic and anti-protozoal effects, can be used for synthesis of novel anti-infective drugs.
6. **Pharmaceutical Compatibility:** Reacts with mild bases to form quinine base, easy for formulation of various dosage forms (tablets, capsules, injections).

### 4. Application Fields

- **Pharmaceutical Industry:** Production of oral/intravenous anti-malarial drugs; raw material for treating malaria and babesiosis in human clinical use.
- **Veterinary Medicine:** Synthesis of veterinary anti-parasitic drugs for livestock/poultry (anti-malaria, anti-babesiosis); pet anti-protozoal formulations.

- **Biomedical Research:** Research reagent for studying anti-malarial drug mechanisms; natural alkaloid model in pharmacology experiments.
- **Fine Chemicals:** Intermediate for synthesis of novel quinine derivatives with enhanced anti-malarial and anti-cancer activity.

## 5. Usage Methods

- **Pharmaceutical Formulation:** Used as active pharmaceutical ingredient (API); formulate into tablets/capsules (100-300mg per unit) with excipients (lactose, starch, magnesium stearate); prepare into injectable solutions (20mg/mL) with water for injection (pH adjusted to 2.0-3.0).
- **Veterinary Formulation:** 5-20 mg/kg body weight (formulated with feed additives); prepare into oral powder/injectable solution for livestock/poultry.
- **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 (avoid ototoxic/neurotoxic 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  $\leq 25^{\circ}\text{C}$  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, food and feed raw materials.
- Avoid high temperature ( $>30^{\circ}\text{C}$ ) and repeated freeze-thaw cycles; aqueous formulations stored at  $2-8^{\circ}\text{C}$  (7-day shelf life).
- 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  $2-8^{\circ}\text{C}$  for research use)

## 7. Safety & Protection

- The product is **harmful if swallowed** and causes skin/serious eye irritation; suspected genotoxicity and potential ototoxic/neurotoxic effects at high exposure.
- **Mandatory PPE** for handling: chemical safety goggles, N95/P95 dust mask, nitrile rubber gloves ( $\geq 0.18\text{mm}$ ), 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 extraction and purification process, low batch-to-batch variation, stable product quality.