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**: Artesunate (青蒿琥酯)
- **CAS Number**: 88495-63-0
- **Formula**: C_{19} H_{28} O_8
- **Formula Weight**: 384.42 g/mol
- **Product Characteristics**: High-purity semi-synthetic artemisinin derivative, core raw material for intravenous/oral anti-malarial drugs with fast-acting anti-parasitic activity and good water solubility (compared with artemisinin/artemether). Off-white crystalline powder, soluble in polar organic solvents, non-toxic at therapeutic dosages, fully biodegradable. Pharmaceutical grade meets CP/USP/EP/GMP standards, stable under recommended storage conditions, the first-line anti-malarial drug raw material for severe malaria treatment.

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

Item	Specification (Pharmaceutical Grade)
Appearance	White to off-white crystalline powder, faint characteristic odor
Assay (Purity)	≥ 99.0% (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
Heavy Metals (Hg)	≤ 0.1 ppm
Melting Point	130-135℃ (decomposition)
Specific Rotation (25℃, MeOH, 1%)	+160° to +170°
Related Substances	≤ 0.8% (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, Pseudomonas aeruginosa: Negative
Solubility	Soluble in methanol (1g/10mL); slightly soluble 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 & GMP Compliance**: ≥99.0% assay, meets international pharmacopoeial and GMP standards, low impurity/heavy metal content, sterile grade available
2. **Fast-Acting Anti-Malarial Activity**: First-line raw material for severe malaria treatment, fast absorption and action, high curative rate
3. **Improved Solubility**: Better water solubility than artemisinin/artemether, suitable for intravenous injection formulation
4. **Safety & Low Toxicity**: No systemic toxicity at therapeutic dosages, no serious side effects, suitable for adult/paediatric clinical use
5. **Good Stability**: 24-month shelf life under cool/dry storage conditions, stable in formulated drug products
6. **Eco-friendly**: Fully biodegradable, no environmental pollution, compliant with global green chemical standards
7. **Versatility**: Used for oral/intravenous anti-malarial drug production, biomedical research and novel artemisinin derivative synthesis

4. Application Fields

- **Pharmaceutical Industry**: Core raw material for severe malaria treatment (intravenous injections); oral anti-malarial tablets/capsules; artemisinin combination therapies (ACTs)
- **Clinical Medicine**: First-line anti-malarial drug for hospital use, paediatric/adult severe malaria treatment
- **Biomedical Research**: Research reagent for anti-malarial, anti-parasitic and anti-cancer mechanism studies
- **Veterinary Medicine**: Anti-parasitic drug raw material for livestock/poultry aquaculture (severe malaria/parasitic diseases)
- **Fine Chemicals**: Intermediate for synthesis of novel water-soluble artemisinin derivatives with enhanced activity

5. Usage Methods

- **Pharmaceutical Formulation**:
  - Intravenous injection: Dissolve in DMSO/propylene glycol, dilute with normal saline/glucose solution (dosage per pharmacopoeia/ clinical guidelines)
  - Oral preparation: Formulate with excipients (mannitol/lactose) for tablets/capsules (50mg/100mg standard dosage)
- **Research Use**: 0.01-5 mM concentration for in vitro cell experiments; dissolve in DMSO/methanol to prepare stock solution

6. Packaging & Storage

Packaging Specifications

- 100 g/bottle (pharmaceutical grade, amber sterile glass bottle with PE liner)
- 1 kg/tin (pharmaceutical/industrial grade, sealed sterile 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 sterile packaging (10g/50g) for research/clinical small-batch orders

Storage Conditions

- Store in a **cool, dry, dark** warehouse with temperature ≤20℃ and relative humidity ≤50%
- Keep container **airtight and sealed** (sterile packaging kept unopened) to prevent moisture absorption and light degradation
- Store separately from strong acids, alkalis, oxidizing agents, heavy metal salts and UV light
- Avoid high temperature (>30℃) and repeated freeze-thaw cycles; formulated solutions stored at 2-8℃

7. Safety & Protection

- The product is non-hazardous; mild eye/skin irritation may occur in sensitive individuals
- **Mandatory PPE** for handling: anti-dust safety goggles, nitrile rubber gloves, N95 dust mask (for large-scale/dust-generating operation); sterile gloves/protective clothing for pharmaceutical grade processing
- Avoid dust inhalation and direct eye/skin contact; wash hands thoroughly with soap and water after handling; sterile operation for pharmaceutical formulation
- In case of eye contact, rinse with plenty of running water for 10-15 minutes; consult a doctor if irritation persists
- Do not ingest raw powder; if large amount is ingested, consult a doctor immediately
- Non-combustible; no special fire/explosion protection required in storage/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)** and GMP compliance document
- Provide **pharmacopoeial compliance documents** (CP/USP/EP) and sterility test reports for pharmaceutical grade products
- Standardized semi-synthesis and purification process, low batch-to-batch variation, stable product quality