

Artesunate CP2010

Batch no YN20231215 Mf date Dec 15 2023 Exp date Dec 14 2025

Mar 05 2024

Molecular Formula $C_{19}H_{28}O_8$ Molecular Weight 384.42 CAS Registry Number 88495-63-0

			Mai oo zozi
Tests	Specifications		Results
Appearance	A white crystalline powder, odorless, practically tasteless		Conforms
Solubility	Freely soluble in ethanol, acetone or chloroform, very slightly soluble in water		Conforms
Identification	IR, HPLC, TLC		Positive
Specific optical rotation			+5. 2°
Melting point	131 ~ 136℃		133. 3 ~ 133. 5°C
Н	3.5 ~ 5.0		4. 0
Chlorides	≤ 0.02%		Conforms
Related substances (HPLC)	Dihydroarteminisin	≤ 0.5%	< 0.05%
	Artemisinin	≤ 0.5%	ND
	Dehydrated dihydroartemisinin	≤ 0.1%	< 0.05%
	Any other single impurity	≤ 0.1%	ND
	Total impurities	≤ 1.5%	0. 05%
Water	≤ 0.5%		0. 08%
Residual on ignition	≤ 0.1%		0. 03%
Heavy metals	≤ 20 ppm		Conforms
Residual solvents	Methanol	≤ 0.3%	ND
	Acetone	≤ 0.5%	0. 01%
	N-hexane	≤ 0. 029%	ND
Microbiological	Total aerobic microbial count		< 1 cfu/gr
	Yeasts & molds	≤ 100 cfu/gr	< 1 cfu/gr
	E.Coli: Negative		Negative
Assay (HPLC) odb	98.0 $^{\sim}$ 102.0% of $C_{19}H_{28}O_{8}$		99. 93%

Packaging & storage	Preserve in tight, light-resistant containers	
Conclusion	Material complies with CP2010	

