

Certificate of Analysis

Product Name	ARTEMISININ	Manufacturing Date	20210203
Batch No.	KN20210203	Test Date	20210215
Quantity	1000KG	Expiry Date	20230202

Items	Requirements	Results
<b>Description</b>		
Appearance:	White to Off-white crystalline powder.	Conforms
Solubility	Freely soluble in acetone and in glacial acetic acid, soluble in methanol, ethanol, dilute ethanol, ether or petroleum ether, practically insoluble in water	Conforms
Melting point	150~153℃	150.9-151.8℃
Specific optical rotation	+75°~+78°	+77.1°
<b>Identification</b>		
Color Reaction	A purple color is produced	Conforms
Color Reaction	A deep violet-red color is produced	Conforms
HPLC	The retention time of main peak in test preparation should match with of that of the working standard as obtained from assay by HPLC test	Conforms
IR	The IR spectrum of the sample should be concordant with the IR spectrum of the artemisinin working standard	Conforms
<b>Tests</b>		
Related Substances (HPLC)	Artemisitene≤ 0.15% 9-epimer of artemisinin≤ 0.3% Any individual impurity≤ 0.15% Total impurities≤ 1.0%	0.07% N.A 0.1% 0.75%
Loss on Drying	Not more than 0.5%	0.25%
Residue on ignition	Not more than 0.1%	0.06%
<b>Heavy metal</b>		
Lead	Not more than 2ppm	Conforms
Arsenic	Not more than 1ppm	Conforms
Mercury	Not more than 0.1ppm	Conforms
Cadmium	Not more than 0.1ppm	Conforms
<b>Microbial limits</b>		
Aerobic bacteria count	Not more than 1000cfu/g	Conforms
Yeast& Mold	Not more than 100cfu/g	Conforms
Escherichia coli	Negative	Conforms
Pseudomonas aeruginosa	Negative	Conforms
Staphylococcus aureus	Negative	Conforms
Assay(HPLC)	98.0% ~102.0% (on dried basis)	98.35%
<b>Conclusion:</b> The product conforms to the in-house standard		

Quality Assurance Officer: 

Corrector: 杨金波

Analyst: 许珂