



### Certificate of Analysis

<b>Product name</b>	Artesunate	<b>Manufacture date</b>	Sep.02.2023
<b>Batch number</b>	FQ230902	<b>Analysis date</b>	Sep.03.2023
<b>Batch quantity</b>	100kg	<b>Expire date</b>	Sep.02.2025

Items	Specification	Results
Appearance	White crystalline powder; odorless.	Confirm
Solubility	Easily soluble in ethanol, acetone or methylene chloride, very slightly soluble in water.	Confirm
TLC	Under sunlight, the position and color of the main spots displayed by the test solution should be consistent with that of the artesunate reference solution.	Confirm
HPLC	The retention time of the main peak of the test sample and the reference substance should be consistent.	Confirm
CI	The infrared absorption spectrum should be consistent with the reference substance	Confirm
Solution Clarity and Color	The solution should be clear and colorless; if it is turbid, compare it with the No. 1 turbidity standard solution and it should not be more concentrated.	Confirm
Chloride	Compared with the control solution, it must not be more turbid ( $\leq 0.02\%$ )	Confirm
Related substances (HPLC)	Dihydroartemisinin $\leq 1.0\%$	N.A
	Artemisinin $\leq 0.5\%$	N.A
	Impurity I $\leq 0.2\%$	0.04%
	Other simple impurities $\leq 0.2\%$	0.09%
	Total impurities $\leq 2.0\%$	0.13%
Moisture	$\leq 0.5\%$	0.48%
Residue on ignition	$\leq 0.1\%$	0.07%
Heavy metal	$\leq 20\text{ppm}$	Confirm
Bacterial endotoxin	$\leq 1.25\text{EU}$	Confirm
Assay(HPLC)	98.0%~102.0%	98.7%

<b>Packing description:</b>	Sealed export grade drum & double of sealed plastic bag
<b>Storage:</b>	Store in a tightly closed container ,in a cool and dry place
<b>Shelf life:</b>	2 years when properly stored

Quality Assurance Officer: 李强

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