



河北言希化工有限公司
HEBEI YANXI CHEMICAL CO., LTD

CERTIFICATE OF ANALYSIS

C.O.A. NO:COA-SPIA-YE2111-1

PRODUCT:SPIRONOLACTONE	BATCH NO: SPICb-Y211001
MFG.DATE: OCT 21,2021	RETEST DATE: OCT 20,2025
PACKING: 20kg/DRUM	QUANTITY:300kg

Item	Specification	Results
Characters	A white or yellowish-white powder.	white powder
Identification	A: IR: Complies with EP	Complies
	B:TLC: Complies with EP	Complies
	C: Chemistry test: complies with EP	Complies
Specific optical rotation	-41°~-46°(10mg/ml in 96% Ethanol)	-43.0°
Related substances (HPLC)	Impurity A≤0.2%	0.02%
	Impurity C≤0.2%	Not found
	Impurity D≤0.15%	0.02%
	Impurity E≤0.3%	Not found
	Impurity F≤0.3%	0.08%
	Impurity I≤0.5%	0.02%
	Any other impurity≤0.10%	Max Imp:0.04%
	Total Impurities≤0.7%	0.14%
Free thiol compound	A blue colour develops	Complies
Loss on drying	Not more than 0.5%	0.1%
Sulphated ash	Not more than 0.1%	<0.1%
Assay	HPLC method:97.5~102.0%	100.1%
Particle size	MIN 25% ≤ 90 microns	100.0%
Conclusion: The sample complies with EP10		

This batch of the above product shall NOT be distributed to European or US market.

