COA 质量检验报告



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CERTIFICATE OF ANALYSIS

Product Name:		Carbocisteine		
Molecular Formula:		C5H9NO4S		HO,
Molecular Weigh:		179.19		S NH ₂
Batch No.:		CF20250112002	CAS No:	638-23-3
Mfg. Date:		2025-01-12		036-23-3
Date of Report:		2025-01-12	Quantity:	2050.354kg
Expired Date:		2027-01-12	Package:	Bag
Item		Specifications		Results
Characters		A white or almost white, crystalline powder, practically in soluble in water and in alcohol. It dissolves in dilute miner al acids and in dilute solutions of alkali hydroxides		Conforms
Identification	Test A (Specific Optical rotation)	It complies with the test for specific optical rotation.		Conforms
	Test C(IR)	It complies with the spectrum obtained with carbocisteine CRS.		Identical
Appearance of solution		Clear and colourless		Clear and colourless
рН		2.8 to 3.0		2.8
Specific optical rotation $_{D}^{^{20}}[\alpha]_{D}^{^{20}}[\alpha]_{D}^{^{20}}$		-32.5° to-35.5°		-34.4°
Related substances		Impurity A(L-Cystine) ≤0.5%		0.12%
		Impurity B(Chloroacetic acid) ≤0.05%		0.01%
		Impurity C	≤0.05%	0.02%

	Impurity D ≤0.2%	0.15%	
Related substances	Any other impurity ≤0.05%	<0.03%	
	Total Impuritie other than A and B ≤0.4%	0.17%	
Chlorides	≤0.15%	<0.10%	
Sulfates	≤300ppm	<300ppm	
Loss on drying	≤0.5%	0.1%	
Sulfated ash	≤0.3%	0.08%	
Assay	98.5 to 101.0%(dried substance) 99.6%		
Conclusion	Comply with the specification of CEP 2022-121-Rev 01		
<u></u> 质检章			