

CERTIFICATE OF ANALYSIS

Product Name:	Carbocisteine	Report Date:	March 30, 2017
Formula:	C ₅ H ₉ NO ₄ S	Batch No.:	170318
CAS No.:	638-23-3	Manu. Date:	March 18, 2017
Inspection Standard:	EP7	Exp. Date:	March 17, 2019

RESULTS OF ANALYSIS

Test Items	Specifications	Results	
Description	A white, crystalline powder, practically insoluble in water, in alcohol and in ether. It dissolves in dilute mineral acids and in dilute solutions of alkali hydroxides	Conforms	
Identification	Test A	Conforms	
	Test B(IR)		The IR spectrum of the sample is concordant with the spectrum of the reference standard, Carbocisteine CRS.
	Test C(TLC)		The principal spot in the chromatogram obtained with the test solution (b) is similar in position, color and size to the principal spot in the chromatogram obtained with the reference solution(a)
	Test D (Chemical reaction)		Dark red color is produced, which changes to brown and then to yellow within a few minutes
pH	2.8 - 3.0	2.8	
Specific optical rotation $[\alpha]_D^{20}$	-32.5° - -35.5°	-33.8°	
State of solution (Transmittance)	Solution is clear and colourless Not less than 95.0%	Conforms 98.9%	
Ninhydrin-positive substances	Not more than 0.5%	Conforms	
Chloride(Cl)	Not more than 0.15%	<0.10%	
Sulfate(SO ₄)	Not more than 0.03%	<0.03%	
Heavy metals(Pb)	Not more than 0.001%	<0.001%	
Loss on Drying	Not more than 0.5%	0.1%	
Residue on ignition(sulfated)	Not more than 0.3%	0.04%	
Assay	98.5% - 101.0 %	99.9%	
Conclusion:	Conforms to the specifications of EP7		

Analyst: **侯健之**Auditor: **辽薛兰**Chief of QC: **于铁梅**