

MOEHS BCN, S.L.

Polígono Industrial Aquiberia

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CERTIFICATE OF ANALYSIS

Product: CARBOCISTEINE Ph. Eur. 10

Code: 71400

Batch Nr: 722

Manufacture: 11/12/2020

Re-test Date: 11/12/2025

Customer: FAC SECUNDUM ARTEM NV

Shipment (Kg): 250,00

Packs: 5

TESTS	SPECIFICATIONS	RESULTS
CHARACTERS Characters	Conforms to Ph. Eur.	Conforms
IDENTIFICATION IR Spectrum	Conforms to Std.	Conforms
Specif. optical rotation (ods)	Complies	Conforms
SPECIFIC TESTS Appearance of solution	Clear and colourless	Conforms
Loss on drying	Maximum 0,5%	0,05 %
pH	2,8 to 3,0	2,9
Specif. optical rotation (ods)	-32,5 to -35,5	-33,4
ORGANIC IMPURITIES Ninhydrin-positive substances		
Each impurity	Maximum 0,5%	< 0,5%
INORGANIC IMPURITIES Sulfated ash	Maximum 0,3%	0,15 %
Chloride	Maximum 0,15%	< 0,15%
Sulfates	Maximum 300 ppm	< 300 ppm
ASSAY Assay (Potent.) (on dried subst.)	98,5% to 101,0%	100,3 %
ADDITIONAL TESTS L-Cysteine	Maximum 0,15%	< 0,15%
ELEMENTAL IMPURITIES Phosphates (periodic test)	Complies ICH Q3D	Complies
Zinc	Maximum 250 ppm	< 250 ppm
	Maximum 10 ppm	< 10 ppm

We hereby certify that the above information is authentic and accurate. This batch has been manufactured, including packaging and quality control, in the above mentioned site in full compliance with the GMP requirements. The batch processing, packaging and analysis records were reviewed and found to be in compliance with ICH Q7, EU GMP Part II and 21 CFR Parts 210 & 211.

Released by QA on 09/02/2021

CoA issued on 15/02/2022

Signed by Quality Control

Cristina Pérez
QC Manager