



## ANALYSIS CERTIFICATE

**Lot/Analysis/Analysis N°: 251362**

Product:	CARBOCYSTEINE
Lot:	251362
Expiry date:	30/04/2028
Reference:	Cumple PhEur11.8
Synonyms:	S-Carboximetil-L-cisteína.3-Carboximetiltioalanina
Formule:	C5H9NO4S
Poids moléculaire:	179.21 g/mol

Assay	Result	Specification	
Identification	Conform (A,B)	Test RFE/Ph. Eur.	
Organoleptic properties	Conform	RFE/Ph. Eur.	
Appearance of solution S	Conform		
pH	3,0	2,8 - 3,0	
Chlorides	< 0,15 %	<= 0,15%	
Sulphates	< 300 ppm	<= 300 ppm	
Specific rotation	-34,4	(-32,5) - (-35,5)	
Substances positive for ninhydrin test	< 0,5 %	<= 0,5%	
Loss on drying	0,04 %	<= 0,5 %	
Sulphated ashes	0,03 %	<= 0,3%	
Assay	99,6 %	98,5 - 101,0 %	
Organic solvents residues	Conform	Test PhEur	#
Elemental impurities	Conform		#
Nitrosamine impurities	Conform		#

Organoleptic characteristics: A white or almost white, crystalline powder, practically insoluble in water and in alcohol. It dissolves in dilute mineral acids and in dilute solutions of alkali hydroxides.

Conservation: In tightly closed containers. Protect from light.

Date of analysis: 01/08/2025

Judgement:  
APPROVED

Responsible: B. Chia

Technical director: Montserrat Enrique

Manufacturer: F00177 PHARMAZELL PRIVATE LTD

Manufacturer batch: 2200005953

Produit	Nom	Capacité	Lot
1118653	CARBOCISTEINA	25 g	251362-G-1
1118653	CARBOCISTEINA	25 g	251362-G-2
1118654	CARBOCISTEINA	100 g	251362-J-1

1118654	CARBOCISTEINA	100 g	251362-J-2
1118657	CARBOCISTEINA	1 kg	251362-P-1
1118657	CARBOCISTEINA	1 kg	251362-P-2

This certificate is not initialled as it is computer processed, it is validated with the originals available at Acofarma.

Original manufacturer's certificate available on request.

(#) Parameter controlled by the manufacturer

(=) UE certificate

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