



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 251968

Product:	ACETYL CYSTEINE
Lot:	251968
Expiry date:	04/05/2028
Reference:	Cumple PhEur11.8
Synonyms:	N-Acetil-3-mercaptoalanina.
Formula:	C5H9NO3S
Molecular weight:	163,2 g/mol

Assay	Result	Specification	
Identification	Conform (A,C)		
Organoleptic properties	Conform		
Appearance of solution S	Conform		
Specific rotation	+23,7	(+21,0) - (+27,0)	
Related substances (HPLC)	Conform		
Zinc	< 10 ppm	<= 10 ppm	
Loss on drying	0,00 %	<= 1,0 %	
Sulphated ashes	0,00 %	<= 0,2 %	
Assay	98,6 %	98,5 - 101,0 %	
Elemental impurities	Conform	Test PhEur	#
Impurity B	< 0,05 %	<= 0,2 %	
Impurity C	< 0,05 %	<= 0,3 %	
Impurity D	< 0,05 %	<= 0,15 %	
Any other impurity	< 0,05 %	<= 0,10 %	
Total impurities	< 0,05 %	<= 0,5 %	
Organic solvents residues	Conform	Test PhEur	#
Nitrosamine impurities	Conform		#

Organoleptic characteristics:

Conservation: In tightly closed containers. Protect from light.

Date of analysis: 17/12/2025

Judgement:
APPROVED

Responsible: B. Chia

Technical director: Montserrat Enrique

Manufacturer: F00312 WUHAN GRAND HOYO CO., LTD

Manufacturer batch: C103-202505830F

Product	Name	Capacity	Batch
1100954	ACETILCISTEINA	25 g	251968-G-1

1100954	ACETILCISTEINA	25 g	251968-G-2
1100955	ACETILCISTEINA	100 g	251968-J-1
1100955	ACETILCISTEINA	100 g	251968-J-2
1100958	ACETILCISTEINA	1 kg	251968-P-1
1100958	ACETILCISTEINA	1 kg	251968-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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