

ACETIL CISTEINA (EUR. PH.)

PRODUCT CODE: 151358	CAS Nº: 616-91-1	ANALYSIS Nº: 288/25
MANUFACTURER BATCH: C103-202505808F	CERTIFICATE ID: 48.190	
SUPPLIER BATCH: ----	MANUFACTURING DATE: 27/04/2025	
METAPH BATCH: 0190925	EXPIRY DATE: 26/04/2028	

ATTRIBUTES	SHOULD BE	IS
Appearance	White or almost white crystalline powder or colorless crystals	White crystalline powder
Solubility	Freely soluble in water and in ethanol (96 %), practically insoluble in methylene chloride	Complies (*)
Identification A	Complies	Complies
Identification C	Complies	Complies
Appearance of solution	Clear and colourless	Clear and colourless
pH	2.0 - 2.8	2.3 (*)
Specific optical rotation	+21.0° / +27.0°	+24.1
Related substances		(*)
Impurity C	=< 0.3 %	< 0.05 %
Impurity B	=< 0.2 %	< 0.05 %
Impurity D	=< 0.15 %	< 0.05 %
Unspecified impurities	=< 0.10 %	< 0.05 %
Total impurities	=< 0.5 %	0.08 %
Zinc	=< 10 ppm	< 5 ppm (*)
Loss on drying	=< 1.0 %	0.08 %
Sulfated ash	=< 0.2 %	0.1 %
Assay	98.5 - 101.0 %	99.8 %

COMPLIES WITH

European Pharmacopoeia 11.0

REMARKS

Acetylcysteine is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline and the requirements of guides EMA/CHMP/ICH/82260/2006 - ICH Q3C (R6) "Residual solvents".

(*) Data adapted from the manufacturer's certificate of analysis.

Absence of N-nitrosamines impurities has been ensured after a risk evaluation according to ICH Q9, ICH M7 and in accordance with guidelines EMA/428592/2019 Rev 2 and EMA/189634/2019.

Certificates of residual solvents, allergens, non-GMO and BSE-TSE, among others, are available upon request.

All methods of analysis are validated by official pharmacopoeias or are validated by internal methods of the manufacturer, which can be obtained at specific request. The above information does not exempt from the obligation to identify the product before use.

STORAGE

Keep tightly closed and in a dry, cool and well-ventilated place.

Analysis date: 26/09/2025
 Signature: Albert Sánchez López (QP)
 Conclusion: Complies

Manufacturer: 40000685

