



TECHNICAL DATA SHEET

889-TDS-ENG-2023

ACETIL CISTEINA (n-acetil l-cisteina) PH.EUR. (GMP)		
DESCRIPTION DCI: ACETYLCYSTEINE		DESCRIPTION DOE: ACETILCISTEINA
CAS Nº: 696-91-1	EC Nº: 210-498-3	AEMPS CODE: 233A
MOL. WEIGHT: 163.19	MOL. FORMULA: C5H9NO3S	ARTICLE CODE: 889

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

COMPLIES WITH

European Pharmacopeia 11.0

STORAGE

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

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".

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.