

TECHNICAL DATA SHEET

46433133-TDS-ENG-2026

ACIDO ALFA LIPOICO (ACIDO TIOCTICO) (EUR. PH.)		
DESCRIPTION DCI: ALPHA-LIPOIC ACID		DESCRIPTION DOE: ALFA-LIPOICO ACIDO
CAS N°: 1077-28-7	EC N°: 214-071-2	AEMPS CODE: 8197A
MOL. WEIGHT: 206,33	MOL. FORMULA: C8H14O2S2	ARTICLE CODE: 46433133

<u>ATTRIBUTES</u>	<u>SHOULD BE</u>
Appearance	Yellow, crystalline powder
Solubility	Very slightly soluble in water, very soluble in dimethylformamide, freely soluble in methanol
Identification	Complies
Appearance of solution	Clear
Impurity B	=< 1.0 %
Related substances	
Impurity A	=< 0.2 %
Unspecified impurities	=< 0.10 %
Total impurities	=< 0.3 %
Loss on drying	=< 0.2 %
Sulfated ash	=< 0.1 %
Assay	97.0 - 102.0 %

COMPLIES WITH

European Pharmacopoeia 12.1

STORAGE

Store in a cool place. Keep the container tightly closed, in a dry, well-ventilated place and protected from light.

REMARKS

Alpha Lipoic Acid 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.