

**ACIDO ALFA LIPOICO (ACIDO TIOTICO) (EUR. PH.)**

PRODUCT CODE: 46433133	CAS Nº: 1077-28-7	ANALYSIS Nº: 316/24
MANUFACTURER BATCH: TTA20241002	CERTIFICATE ID: 44.412	
SUPPLIER BATCH: ----	MANUFACTURING DATE: 11/10/2024	
METAPH BATCH: 0031224	EXPIRY DATE: 10/10/2027	

ATTRIBUTES	SHOULD BE	IS
Appearance	Yellow, crystalline powder	Yellow, crystalline powder
Solubility	Very slightly soluble in water, very soluble in dimethylformamide, freely soluble in methanol	Complies (*)
Identification	Complies	Complies
Appearance of solution	Clear	Clear
Impurity B	=< 1.0 %	< 1.0 %
Related substances		
Impurity A	=< 0.2 %	Not Detected
Unspecified impurities	=< 0.10 %	< 0.05 %
Total impurities	=< 0.3 %	< 0.05 %
Loss on drying	=< 0.2 %	0.05 %
Sulfated ash	=< 0.1 %	0.02 %
Assay	97.0 - 102.0 %	99.7 %

**COMPLIES WITH**

European Pharmacopoeia 11.0

**REMARKS**

Product fully analyzed within the EU, in compliance with the current regulations "EudraLex - Volume 4 - Good Manufacturing Practice (GMP) guidelines" Part-II.

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".

(\*) 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**

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

Analysis date: 06/02/2025  
Signature: Albert Sánchez López (QP)  
Conclusion: Complies  
Original certificate available upon request

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