



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 242242

Product:	THIOCTIC ACID
Lot:	242242
Expiry date:	28/02/2027
Reference:	Especificaciones de fabricante
Synonyms:	Ácido alfa-lipoico. Ác. 1,2-ditiolano-3-pentanoico
Formula:	C8H14O2S2
Molecular weight:	206,33 g/mol

Assay	Result	Specification	
Identification	Conform (A,B)	Test USP	
Organoleptic properties	Conform		
Melting point	61,7 °C		=
Specific rotation	0°	(-1,0°) - (+1,0°)	=
Heavy metals	<= 10 ppm	< =10 ppm	=
Cromatographic purity	Conform	Test USP	=
Loss on drying	0,03 %	<= 0,2 %	
Residue on ignition	0,01 %	<= 0,1%	=
Assay (HPLC)	98,6 %	98,0 - 101,0 %	
Single impurity	0,02 %	<= 0,1 %	=
Total impurities	0,04 %	<= 2,0 %	=
Residual solvent: Cyclohexane	<= 3880 ppm	<= 3880 ppm	#
Residual solvent: Ethyl acetate	<= 5000 ppm	<= 5000 ppm	#
Residual solvent: Toluene	<= 890 ppm	<= 890 ppm	#

Organoleptic characteristics:

Conservation: In tightly closed containers. Protect from light.

Date of analysis: 09/12/2024

Judgement:
APPROVED

Responsible: B. Chia

Technical director: Montserrat Enrique

Manufacturer: F00331 SUZHOU FUSHILAI PHARMACEUTICA CO., LTD.

Manufacturer batch:

Product	Name	Capacity	Batch
1102686	ACIDO TIOCTICO	25 g	242242-G-1
1102688	ACIDO TIOCTICO	100 g	242242-J-1
1102688	ACIDO TIOCTICO	100 g	242242-J-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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