



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 251043

| | |
|-------------------|--|
| Product: | THIOCTIC ACID |
| Lot: | 251043 |
| Expiry date: | 30/09/2027 |
| 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 | 61,8 °C | | = |
| Specific rotation | 0° | (-1,0°) - (+1,0°) | = |
| Heavy metals | <= 10 ppm | < =10 ppm | = |
| Cromatographic purity | Conform | Test USP | = |
| Loss on drying | 0,07 % | <= 0,2 % | |
| Residue on ignition | 0,02 % | <= 0,1% | = |
| Assay (HPLC) | 99,0 % | 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: 22/05/2025

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 | 251043-G-1 |
| 1102686 | ACIDO TIOCTICO | 25 g | 251043-G-2 |
| 1102688 | ACIDO TIOCTICO | 100 g | 251043-J-1 |
| 1102688 | ACIDO TIOCTICO | 100 g | 251043-J-2 |

1102691

ACIDO TIOCTICO

1 kg

251043-P-1

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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