

CERTIFICATE OF ANALYSIS

Our Ref. : F24/3028-01

Our Sample Id. : 94905

Metapharmaceutical Industrial SL
Josep Pia 163, 2° 5a
08020 Barcelona
SPAIN

Product : Tiopronin

Lot number : 0101224

Customer product number : 1805

Customer reference : N/A

Date of application : 20/12/2024

Date of reception : 20/12/2024

Date start of analysis : 02/01/2025

Date of end of analysis : 10/01/2025

Test Method : ANA-META-001/1

Spec Reference : Customer

PERFORMED ANALYSIS AND RESULTS

Analysis	Specification	Result
Aspect		
Appearance	A white crystalline powder, special smell, tastes sour.	Complies
Appearance of solution	The solution is clear and colorless.	Complies
Identifications		
Identification B (reaction)	A red color develops.	POSITIVE
Identification C (reaction)	A red-brown or brown develops.	POSITIVE
Other tests		
Melting point	96 - 99 °C	97.8 °C
Sulfate	NMT 0.048%	Complies
Iron (ICP-MS)	NMT 0.0005 %	0.0005 %
Arsenic (ICP-MS)	NMT 2 ppm	<0.46 ppm
Related substance (TLC)	NMT 2.0%	Complies
Loss on drying (Ph.Eur. 2.2.32)	NMT 0.5 %	0.04 %
Sulfated ash (Ph.Eur.2.4.14)	NMT 0.1 %	0.07 %
Heavy metals		
Lead (ICP-MS)	NMT 20 ppm	1 ppm
Mercury (ICP-MS)	NMT 20 ppm	<0.08 ppm
Cadmium (ICP-MS)	NMT 20 ppm	<0.11 ppm
Residual solvents		
Ethyl acetate (GC)	NMT 5000 ppm	114 ppm

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PERFORMED ANALYSIS AND RESULTS

Analysis	Specification	Result
Assays		
Assay Tiopronin (titration)	NLT 98.0% (dried basis)	99.6 %
± CI (95% Confidence interval)		0.3 %

CONCLUSION : The sample complies with the specifications of the performed analysis.

Issued By: Ingrid Van den Broeck

Patsy Peeters

Office Manager/HR

Industrial Pharmacist, QP

Date of Issue: 10/01/2025

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