

**TRILOSTANO (USO VETERINARIO)**

PRODUCT CODE: 0110	CAS Nº: 13647-35-3	ANALYSIS Nº: 271/23
MANUFACTURER BATCH: LK38-2305002	CERTIFICATE ID: 40.152	
SUPPLIER BATCH: ----	MANUFACTURING DATE: 01/05/2023	
METAPH BATCH: 0081123	RETEST DATE: 31/05/2026	

ATTRIBUTES	SHOULD BE	IS
Appearance	White to off-white powder	White powder
Identification	Complies	Complies
Assay	=> 99.0 %	99.9 %
Individual impurities	=< 0.30 %	< 0.05 %
Loss on drying	=< 0.50 %	0.27 %
Residue on ignition	=< 0.10 %	0.04 %
Water	=< 0.50 %	0.22 %
Specific optical rotation	+137.0 / +139.0	+138.5
Residual solvents		
Tetrahydrofuran	<= 720 ppm	< 50 ppm
tert-butyl methyl ether	<= 5000 ppm	< 50 ppm
Ethanol	<= 5000 ppm	82 ppm
Dimethyl Sulfoxide	<= 5000 ppm	< 50 ppm
Methylene Chloride	<= 600 ppm	< 50 ppm
Microbiological control		
TAMC	=< 1000 CFU/g	< 10 CFU/g
TYMC	=< 100 CFU/g	< 10 CFU/g
Escherichia coli	Absence/1g	Absence/1g
Candida Albicans	Absence/1g	Absence/1g
Pseudomonas aeruginosa	Absence/1g	Absence/1g
Staphylococcus aureus	Absence/1g	Absence/1g
Salmonella	Absence/1g	Absence/1g

**COMPLIES WITH**

Manufacturer Specifications

**REMARKS**

Trilostane 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".

All data controlled by Metapharmaceutical Industrial SL.

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**

Keep the container tightly closed in a fresh and well-ventilated place.

Analysis date: 19/12/2023  
Signature: Albert Sánchez López (QP)  
Conclusion: Complies  
Original certificate available upon request

Manufacturer: 40000757  
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