



TRILOSTANO (USO VETERINARIO)

PRODUCT CODE: 0110	CAS Nº: 13647-35-3	ANALYSIS Nº: 032/25
MANUFACTURER BATCH: 241001	CERTIFICATE ID: 45.045	
SUPPLIER BATCH: ----	MANUFACTURING DATE: 20/10/2024	
METAPH BATCH: 0060225	RETEST DATE: 19/10/2027	

ATTRIBUTES	SHOULD BE	IS
Appearance	White to off-white powder	White powder
Solubility	Soluble in dimethyl sulfoxide, soluble in pyridine, slightly soluble in ethanol, slightly soluble in water	Complies (*)
Identification	Complies	Complies
Melting point	257 - 270 °C	262 °C
Related impurities	=< 1.0 %	0.93 % (#)
Loss on drying	=< 0.50 %	0.2 %
Residue on ignition	=< 0.10 %	0.06 %
Specific optical rotation	+137.0 / +139.0	+ 137.5
Heavy metals	=< 20 ppm	< 20 ppm (*)
Assay	=> 99.0 %	99.1 %
Residual solvents		
Ethanol	<= 5000 ppm	106 ppm
Methylene Chloride	<= 600 ppm	< 50 ppm
Methanol	<= 3000 ppm	92 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

(#) Impurities detailed underneath:

RT (4.81 min) = 0.01 %

RT (9.99 min) = 0.04 %

RT (12.43 min) = 0.07 %

RT (17.09 min) = 0.82 %

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

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".

(*) 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.

Analysis date: 26/03/2025

Signature: Albert Sánchez López (QP)

Conclusion: Complies

Original certificate available upon request

Manufacturer: 40000561

GUANGZHOU TOPWORK CHEMICAL CO., LTD

A6013,6016,No. 18,Building 1,Yinli Street,Shatai

South Road

510630 Tianhe District



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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.

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