METAPHARMACEUTICAL IND SL
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TECHNICAL DATA SHEET

0110-TDS-ENG-2023

TRILOSTANO (USO VETERINARIO)		
DESCRIPTION DCI: TRILOSTANE	DESCRIPTION DOE: TRILOSTANO	
CAS Nº: 13647-35-3	EC Nº: 237-133-0	AEMPS CODE: 2378A
MOL. WEIGHT: 329.43	MOL. FORMULA: C20H27NO3	ARTICLE CODE: 0110

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

COMPLIES WITH

Manufacturer Specifications

STORAGE

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

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".

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

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product before use.