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TECHNICAL DATA SHEET

002540-TDS-ENG-2023

IVERMECTINA EP (USO HUMANO)		
DESCRIPTION DCI: IVERMECTIN	DESCRIPTION DOE: IVERMECTINA	
CAS Nº: 70288-86-7	EC Nº: 274-536-0	AEMPS CODE: 7778A
MOL. WEIGHT: 1736.16	MOL. FORMULA: C95H146O28	ARTICLE CODE: 002540

ATTRIBUTES	SHOULD BE
Appearance	White or yellowish-white, crystalline powder, slightly hygroscopic
Solubility	Practically insoluble in water, freely soluble in methylene chloride, soluble in ethanol (96 %)
Identification A	Complies
Identification B	Complies
Appearance of solution	Clear and not more intensely coloured than ref. sol. BY7
Specific optical rotation	-20 / -17
Related substances	
Impurity with a relative retention of 1.3 to 1. 5	=< 2.5 %
Any other impurity	=< 1 %
Total impurities	=< 5 %
Ethanol and formamide	
Ethanol	=< 5.0 %
Formamide	=< 3.0 %
Water	=< 1.0 %
Sulfated ash	=< 0.1 %
Assay	
Ivermectin (H2B1a + H2B1b)	95.0 - 102.0 %
Ratio H2B1a/(H2B1a + H2B1b)	=> 90.0 %

COMPLIES WITH

European Pharmacopoeia 11.0

STORAGE

Keep the container tightly closed in a dry and cool place.

REMARKS

Ivermectin is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline and the requirements of guides EMA/CHMP/ICH/82260/2006.

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.