METAPHARMACEUTICAL IND SL
Josep Plà, 163, 2n 5a / Tel. 933 089 976 / info@metapharmaceutical.com

IVERMECTINA USO HUMANO (EUR. PH.)

PRODUCT CODE: 002540	CAS Nº: 70288-86-7	ANALYSIS Nº: 058/25	
MANUFACTURER BATCH:	4025021N240906	CERTIFICATE ID:	45.481
SUPPLIER BATCH:	----	MANUFACTURING DATE:	26/09/2024
METAPH BATCH:	0110325	RETEST DATE:	25/09/2027

ATTRIBUTES	SHOULD BE	IS
Appearance	White or yellowish-white, crystalline powder, slightly hygroscopic	White crystalline powder, slightly hygroscopic
Identification A	Complies	Complies
Identification B	Complies	Complies
Appearance of solution	Clear and not more intensely coloured than ref. sol. BY7	Complies
Specific optical rotation	-20 / -17	-17
Related substances		
Impurity with a relative retention of 1.3 to 1. 5	=< 2.5 %	< 2.5 % (#1)
Any other impurity	=< 1 %	< 1 % (#2)
Total impurities	=< 5 %	1.9 %
Ethanol and formamide		
Ethanol	=< 5.0 %	4.3 %
Formamide	=< 3.0 %	2.9 %
Water	=< 1.0 %	0.3 %
Sulfated ash	=< 0.1 %	0.04 %
Assay		
Ivermectin (H2B1a + H2B1b)	95.0 - 102.0 %	100.4 %
Ratio H2B1a/(H2B1a + H2B1b)	=> 90.0 %	99.8 %

COMPLIES WITH

European Pharmacopoeia 11.0

REMARKS

(#1) Impurities with a relative retention of 1.3 to 1.5 detailed underneath:
RT (40.41 min) = 0.23 %
RT (43.82 min) = 0.92 %

(#2) Any other impurity detailed underneath:
RT (7.11 min) = 0.05 %
RT (14.09 min) = 0.20 %
RT (14.77 min) = 0.12 %
RT (15.59 min) = 0.13 %
RT (17.68 min) = 0.21 %

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

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,

Analysis date: 12/03/2025
Signature: Albert Sánchez López (QP)
Conclusion: Complies
Original certificate available upon request

Manufacturer: 40000285
HISUN PHARMACEUTICAL (HANGZHOU) Co. Ltd.
Xialian Village, Xukou Town
Fuyang City
310000 Hangzhou City

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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 dry and cool place.

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