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: 120/25	
MANUFACTURER BATCH:	4025021N240906	CERTIFICATE ID:	46.385
SUPPLIER BATCH:	----	MANUFACTURING DATE:	26/09/2024
METAPH BATCH:	0060525	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	-19
Related substances		
Impurity with a relative retention of 1.3 to 1. 5	=< 2.5 %	0.9 %
Any other impurity	=< 1 %	< 1.0 % (#)
Total impurities	=< 5 %	2.2 %
Ethanol and formamide		
Ethanol	=< 5.0 %	2.5 %
Formamide	=< 3.0 %	1.5 %
Water	=< 1.0 %	0.2 %
Sulfated ash	=< 0.1 %	0.09 %
Assay		
Ivermectin (H2B1a + H2B1b)	95.0 - 102.0 %	99.0 %
Ratio H2B1a/(H2B1a + H2B1b)	=> 90.0 %	99.8 %

COMPLIES WITH

European Pharmacopoeia 11.0

REMARKS

(#) Impurities detailed underneath:
RT (6.15 min) = 0.06 %
RT (10.65 min) = 0.39 %
RT (11.53 min) = 0.19 %
RT (12.76 min) = 0.25 %
RT (26.73 min) = 0.19 %
RT (39.17 min) = 0.07 %

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

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, which can be obtained at specific request. The above information does not exempt from the obligation to identify the product before use.

Analysis date: 24/07/2025
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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STORAGE

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

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