



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 251989

Product:	IVERMECTIN
Lot:	251989
Expiry date:	24/06/2028
Reference:	Cumple PhEur11.8
Synonyms:	
Formula:	C ₄₈ H ₇₄ O ₁₄ + C ₄₇ H ₇₂ O ₁₄
Molecular weight:	g/mol

Assay	Result	Specification	
Identification	Conform (A,B)	Test PhEur (A,B)	
Organoleptic properties	Conform	PhEur	
Appearance of toluene solution 2%	Conform		
Specific rotation	-17,6°	(-17,0°) - (-20,0°)	
Related substances (HPLC)	Conform		
Ethanol and formamide	Conform	Test PhEur	
Heavy metals	<= 20 ppm	<= 20 ppm	#
Moisture - K.F. (s/0,5g)	0,07 %	<= 1,0%	
Sulphated ashes	0,02 %	<= 0,1%	
H2B1a/(H2B1a + H2B1b) Ratio	99%	>= 90%	
Assay (HPLC)	98,3 %	95,0-102,0%	
Impurities with relative retention time 1.3-1.5	0,96 %	<= 2,5 %	
Any other impurity	0,28 %	<= 1 %	
Total impurities	2 %	<= 5 %	
Residual solvent: formamide	1,7 %	<= 3,0 %	
Residual solvent: Ethanol	4,0 %	<= 5,0 %	

Organoleptic characteristics: White or yellowish-white crystalline powder, slightly hygroscopic. Pract. insoluble in water, freely soluble in methylene chloride, soluble in ethanol 96%.

Conservation: In tightly closed containers. Protect from light.

Date of analysis: 05/12/2025

Judgement:
APPROVED

Responsible: B. Chia

Technical director: Montserrat Enrique

Manufacturer: F00071 ZHEJIANG HISUN PHARMACEUTICAL CO. LTD.

Manufacturer batch: 4025021N250608

Product	Name	Capacity	Batch
1160030	IVERMECTINA Uso Humano	1 g	251989-D-1

1160030	IVERMECTINA Uso Humano	1 g	251989-D-2
1160031	IVERMECTINA Uso Humano	5 g	251989-E-1
1160031	IVERMECTINA Uso Humano	5 g	251989-E-2
1160032	IVERMECTINA Uso Humano	25 g	251989-G-1
1160032	IVERMECTINA Uso Humano	25 g	251989-G-2
1160034	IVERMECTINA Uso Humano	100 g	251989-J-1
1160034	IVERMECTINA Uso Humano	100 g	251989-J-3
1160035	IVERMECTINA Uso Humano	250 g	251989-N-1
1370277	IVERMECTINA Uso Humano (FLB)	100 g	251989-J-2

This certificate is not initialled as it is computer processed, it is validated with the originals available at Acofarma.

Original manufacturer's certificate available on request.

(#) Parameter controlled by the manufacturer

(=) UE certificate

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Date of edition: 19/05/2026

