



## ANALYSIS CERTIFICATE

**Lot/Analysis/Analysis N°: 250273**

Product:	IVERMECTIN
Lot:	250273
Expiry date:	06/10/2027
Reference:	Cumple PhEur11.6
Synonyms:	
Formula:	C <sub>48</sub> H <sub>74</sub> O <sub>14</sub> + C <sub>47</sub> H <sub>72</sub> O <sub>14</sub>
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	-17,5°	(-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)	0,06 %	<= 1,0%	
Sulphated ashes	0,00 %	<= 0,1%	
H2B1a/(H2B1a + H2B1b) Ratio	100 %	>= 90%	
Assay (HPLC)	98,8 %	95,0-102,0%	
Impurities with relative retention time 1.3-1.5	0,87 %	<= 2,5 %	
Any other impurity	0,31 %	<= 1 %	
Total impurities	2 %	<= 5 %	
Residual solvent: formamide	2,2 %	<= 3,0 %	
Residual solvent: Ethanol	4,4 %	<= 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: 05/03/2025

Judgement:  
APPROVED

Responsible: B.Chia

Technical director: Montserrat Enrique

Manufacturer: F00071 ZHEJIANG HISUN PHARMACEUTICAL CO. LTD.

Manufacturer batch: 4025021N241002

Product	Name	Capacity	Batch
1160030	IVERMECTINA Uso Humano	1 g	250273-D-1

1160030	IVERMECTINA Uso Humano	1 g	250273-D-2
1160031	IVERMECTINA Uso Humano	5 g	250273-E-1
1160031	IVERMECTINA Uso Humano	5 g	250273-E-2
1160032	IVERMECTINA Uso Humano	25 g	250273-G-1
1160032	IVERMECTINA Uso Humano	25 g	250273-G-2
1160034	IVERMECTINA Uso Humano	100 g	250273-J-1

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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