



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 233713

Product:	IVERMECTIN veterinary use
Lot:	233713
Expiry date:	19/07/2026
Reference:	Cumple PhEur11.2
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 solution	Conform	Test PhEur	
Specific rotation	-17,4	(-17,0) - (-20,0)	
Related substances (HPLC)	Conform	Test PhEur	
Ethanol and formamide	Conform	Test PhEur	
Elemental impurities	Conform	Test PhEur	#
Moisture - K.F.	0,13 %	<= 1,0 %	
Sulphated ashes	0,00 %	<= 0,1%	
H2B1a/(H2B1a + H2B1b) Ratio	100,0 %	>= 90%	
Assay (HPLC)	95,7 %	95,0-102,0%	
Impurities with relative retention time 1.3-1.5	0,9 %	<= 2,5 %	
Any other impurity	0,43 %	<= 1 %	
Total impurities	2,2 %	<= 5 %	
Residual solvent: Toluene	<= 890 ppm	<= 890 ppm	#
Residual solvent: Methanol	<=3000 ppm	<= 3000 ppm	#

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: 05/12/2023

Judgement:
APPROVED

Responsible: M. Mesa

Technical director: Montserrat Enrique

Manufacturer: F00422 SHANDONG QILU KING-PHAR PAHRMACEUTICAL CO., LTD.

Manufacturer batch: 03230030

Product	Name	Capacity	Batch
1160000	IVERMECTINA Uso Veterinario	25 g	233713-G-1

1160000	IVERMECTINA Uso Veterinario	25 g	233713-G-2
1160000	IVERMECTINA Uso Veterinario	25 g	233713-G-4
1160000	IVERMECTINA Uso Veterinario	25 g	233713-G-5
1160000	IVERMECTINA Uso Veterinario	25 g	233713-G-6
1160005	IVERMECTINA Uso Veterinario	1 kg	233713-P-1
1160005	IVERMECTINA Uso Veterinario	1 kg	233713-P-2
1160005	IVERMECTINA Uso Veterinario	1 kg	233713-P-3
1160005	IVERMECTINA Uso Veterinario	1 kg	233713-P-4
1400335	IVERMECTINA Uso Veterinario (INACTIVO)	5 g	233713-E-1
1400335	IVERMECTINA Uso Veterinario (INACTIVO)	5 g	233713-E-2
1400335	IVERMECTINA Uso Veterinario (INACTIVO)	5 g	233713-E-4

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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