



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 214918

Product:	FLUCONAZOLE
Lot:	214918
Expiry date:	01/03/2026
Reference:	Cumple PhEur10.5
Synonyms:	
Formula:	C ₁₃ H ₁₂ F ₂ N ₆ O
Molecular weight:	306,27 g/mol

Assay	Result	Specification	
Identification	Conform	Test PhEur	
Organoleptic properties	Conform	PhEur	
Appearance of MeOH 5% solution	Conform		
Related substances (HPLC)	Conform		
Heavy metals	<= 10 ppm	<= 10 ppm	#
Loss on drying (1 g, 105°C)	0,08 %	<= 0,5%	
Sulphated ashes	0,01 %	<= 0,1 %	
ASSAY (anhydrous vehicle PFP)	99,9 %	99,0 - 101,0 %	
Impurity A	<= 0,05 %	<= 0,4 %	
Impurity B	<= 0,05 %	<= 0,3 %	
Impurity C	<= 0,05 %	<= 0,15 %	
Unspecified Impurities	<= 0,05 %	<= 0,10 %	
Total impurities	<= 5000 ppm	<= 0,6 %	
Residual solvent: Isopropanol	<= 5000 ppm	<= 5000 ppm	#

Organoleptic characteristics: White or almost white crystalline powder, hygroscopic. Slightly soluble in water, freely soluble in methanol, soluble in acetone.

Conservation: In tightly closed containers. Protect from light.

Date of analysis: 15/09/2021

Judgement:
APPROVED

Responsible: M. Mesa

Technical director: Montserrat Enrique

Manufacturer: F01004 INKE, S.A.

Manufacturer batch: P-159

Product	Name	Capacity	Batch
1145000	FLUCONAZOL	25 g	214918-G-1
1145001	FLUCONAZOL	5 g	214918-E-1
1145001	FLUCONAZOL	5 g	214918-E-2

1145001	FLUCONAZOL	5 g	214918-E-3
1145007	FLUCONAZOL	500 g	214918-O-1
1370132	FLUCONAZOL (FLB) (INACTIVO)	1 g	214918-D-1
1370132	FLUCONAZOL (FLB) (INACTIVO)	1 g	214918-D-2
1370134	FLUCONAZOL (FLB) (INACTIVO)	10 g	214918-F-1
1370134	FLUCONAZOL (FLB) (INACTIVO)	10 g	214918-F-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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