



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 231798

Product:	FLUCONAZOLE
Lot:	231798
Expiry date:	28/02/2027
Reference:	Cumple PhEur11.1
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 solution	Conform	Test PhEur	=
Related substances (HPLC)	Conform		=
Elemental impurities	Conform	Test PhEur	#
Loss on drying	0,05 %	<= 0,5 %	
Sulphated ashes	0,00 %	<= 0,1 %	=
Assay	100,1 %	99,0 - 101,0 %	
Impurity A	< 0,05 %	<= 0,4 %	=
Impurity B	< 0,05 %	<= 0,3 %	=
Impurity C	< 0,05 %	<= 0,15 %	=
Unspecified Impurities	< 0,10 %	<= 0,10 %	=
Total impurities	0,00 %	<= 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: 19/04/2023

Responsible: M. Mesa

Technical director: Montserrat Enrique

Manufacturer: F01004 INKE, S.A.

Manufacturer batch: P-160

Judgement:
APPROVED

Product	Name	Capacity	Batch
1145000	FLUCONAZOL	25 g	231798-G-1
1145000	FLUCONAZOL	25 g	231798-G-2
1145000	FLUCONAZOL	25 g	231798-G-3

1145001	FLUCONAZOL	5 g	231798-E-1
1145001	FLUCONAZOL	5 g	231798-E-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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