



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 220133

Product:	FLUCONAZOLE
Lot:	220133
Expiry date:	01/03/2026
Reference:	Cumple PhEur10.6
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)	0,01 %	<= 0,5%	
Sulphated ashes	0,00 %	<= 0,1 %	=
ASSAY (anhydrous vehicle PFP)	100,2 %	99,0 - 101,0 %	
Impurity A	<= 0,4 %	<= 0,4 %	=
Impurity B	<= 0,3 %	<= 0,3 %	=
Impurity C	<= 0,15 %	<= 0,15 %	=
Unspecified Impurities	<= 0,10 %	<= 0,10 %	=
Total impurities	<= 0,5 %	<= 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: 23/03/2022

Responsible: C. Codina

Technical director: Montserrat Enrique

Manufacturer: F01004 INKE, S.A.

Manufacturer batch: P-159

Judgement:
APPROVED

Product	Name	Capacity	Batch
1145000	FLUCONAZOL	25 g	220133-G-1
1145000	FLUCONAZOL	25 g	220133-G-2
1145001	FLUCONAZOL	5 g	220133-E-1

1145001	FLUCONAZOL	5 g	220133-E-2
1370134	FLUCONAZOL (FLB) (INACTIVO)	10 g	220133-F-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

ACOFARMA DISTRIBUCIÓN, S.A.

C/ Llobregat, 20 - 08223 Terrassa (Barcelona)

Tel./ 93-736.00.88

www.acofarma.com

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