



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 250494

Product:	FLUCONAZOLE
Lot:	250494
Expiry date:	30/11/2029
Reference:	Cumple PhEur11.6
Synonyms:	
Formule:	C ₁₃ H ₁₂ F ₂ N ₆ O
Poids moléculaire:	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	0,10 %	<= 0,5 %	
Sulphated ashes	0,00 %	<= 0,1 %	=
Assay	100,7 %	99,0 - 101,0 %	
Nitrosamine impurities	Conform		#
Impurity A	0,23 %	<= 0,4 %	=
Impurity B	0,01 %	<= 0,3 %	=
Impurity C	ND	<= 0,15 %	=
Unspecified Impurities	< 0,05 %	<= 0,10 %	=
Total impurities	0,24 %	<= 0,6 %	=
Residual solvent: Isopropanol	< 5000 ppm	<= 5000 ppm	#
Residual solvent: methylene chloride	< 600 ppm	<= 600 ppm	#
Residual solvent: Ethyl acetate	< 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: 05/03/2025

Judgement:
APPROVED

Responsible: B. Chia

Technical director: Montserrat Enrique

Manufacturer: F01043 VIRUPAKSHA ORGANICS LTD.

Manufacturer batch: AFLUC24120

Produit	Nom	Capacité	Lot
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1145000	FLUCONAZOL	25 g	250494-G-1
1145001	FLUCONAZOL	5 g	250494-E-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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