



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 223682

Product:	ITRACONAZOLE
Lot:	223682
Expiry date:	28/02/2027
Reference:	Cumple PhEur 10.8
Synonyms:	
Formula:	C ₃₅ H ₃₈ Cl ₂ N ₈ O ₄
Molecular weight:	706 g/mol

Assay	Result	Specification	
Identification	Conform		
Organoleptic properties	Conform	PhEur	
Appearance of solution	Conform		
Related substances (HPLC)	Conform		
Loss on drying	0,01 %	<= 0,5 %	
Sulphated ashes	0,04 %	<= 0,1 %	
Assay	100,4 %	99,0 - 101,0 %	
Elemental impurities	Conform	Test PhEur	#
Impurity B	< 0,05 %	<= 0,3 %	
Impurity E	< 0,05 %	<= 0,2 %	
Impurity G	< 0,05 %	<= 0,3 %	
Sum of impurities C and D	< 0,05 %	<= 0,3 %	
Unspecified Impurities	< 0,05 %	<= 0,10 %	
Total impurities	< 0,05 %	<= 0,8 %	
Residual solvent: Tetrahydrofuran	< 720 ppm	<= 720 ppm	#
Residual solvent: Methanol	< 3000 ppm	<= 3000 ppm	#

Organoleptic characteristics: White or almost white powder. Practically insoluble in water, freely soluble in methylene chloride, very slightly soluble in ethanol (96 per cent).

Conservation: In tightly closed containers. Protect from light.

Date of analysis: 08/08/2022

Judgement:
APPROVED

Responsible: M. Mesa

Technical director: Montserrat Enrique

Manufacturer: F00393 QUÍMICA SINTÉTICA, S.A.

Manufacturer batch: KD0A2311

Product	Name	Capacity	Batch
1100122	ITRACONAZOL	10 g	223682-F-1

1100122	ITRACONAZOL	10 g	223682-F-2
1100123	ITRACONAZOL (INACTIVO)	25 g	223682-G-1
1100124	ITRACONAZOL	100 g	223682-J-1
1100125	ITRACONAZOL	250 g	223682-N-1
1100125	ITRACONAZOL	250 g	223682-N-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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Date of edition: 19/04/2026