



## ANALYSIS CERTIFICATE

**Lot/Analysis/Analysis N°: 232329**

Product:	ITRACONAZOLE
Lot:	232329
Expiry date:	30/04/2028
Reference:	Cumple PhEur11.1
Synonyms:	
Formula:	C <sub>35</sub> H <sub>38</sub> Cl <sub>2</sub> N <sub>8</sub> O <sub>4</sub>
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	0,00 %	<= 0,1 %	
Assay	100,6 %	99,0 - 101,0 %	
Elemental impurities	Conform	Test PhEur	#
Impurity B	0,10 %	<= 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	0,10 %	<= 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: 15/05/2023

Judgement:  
APPROVED

Responsible: M. Mesa

Technical director: Montserrat Enrique

Manufacturer: F00393 QUÍMICA SINTÉTICA, S.A.

Manufacturer batch: KD0A3314

Product	Name	Capacity	Batch
1100122	ITRACONAZOL	10 g	232329-F-1

1100125	ITRACONAZOL	250 g	232329-N-1
1100127	ITRACONAZOL	1 kg	232329-P-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

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