



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 251386

Product:	CLOTRIMAZOLE
Lot:	251386
Expiry date:	30/05/2031
Reference:	Cumple PhEur11.8
Synonyms:	Clotritilimidazol.
Formula:	C ₂₂ H ₁₇ CIN ₂
Molecular weight:	344,82 g/mol

Assay	Result	Specification	
Identification	Conform (B)		
Organoleptic properties	Conform		
Related substances (HPLC)	Conform		=
Loss on drying	0,08 %	<= 0,5 %	
Sulphated ashes	0,00 %	<= 0,1 %	=
Assay	99,8 %	98,5 - 100,5 %	
Elemental impurities	Conform	Test PhEur	#
Impurity A	< 0,05 %	<= 0,2 %	=
Impurity B	< 0,05 %	<= 0,2 %	=
Impurity D	< 0,05 %	<= 0,2 %	=
Impurity E	< 0,05 %	<= 0,2 %	=
Impurity F	< 0,05 %	<= 0,1 %	=
Unspecified Impurities	< 0,10 %	<= 0,10 %	=
Total impurities	< 0,05 %	<= 0,5 %	=
Residual solvent: acetone	< 5000 ppm	<= 5000 ppm	#
Residual solvent: Benzene	< 2 ppm	<= 2 ppm	#
Residual solvent: methylene chloride	< 600 ppm	<= 600 ppm	#

Organoleptic characteristics: White or yellowish-white crystalline powder. Practically insoluble in water, soluble in 96% ethanol and in methylene chloride.

Conservation: In tightly closed containers. Protect from light.

Date of analysis: 15/07/2025

Judgement:
APPROVED

Responsible: B. Chia

Technical director: Montserrat Enrique

Manufacturer: F00406 ERREGIERRE S.p.A.

Manufacturer batch: B250014

Product	Name	Capacity	Batch
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1120253	CLOTRIMAZOL	5 g	251386-E-1
1120253	CLOTRIMAZOL	5 g	251386-E-2
1120255	CLOTRIMAZOL	25 g	251386-G-1
1120255	CLOTRIMAZOL	25 g	251386-G-2
1120260	CLOTRIMAZOL	1 kg	251386-P-1
1200135	CLOTRIMAZOL	100 g	251386-J-1
1200135	CLOTRIMAZOL	100 g	251386-J-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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