



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 224768

Product:	TERBINAFINE HYDROCHLORIDE
Lot:	224768
Expiry date:	19/07/2026
Reference:	Cumple PhEur 10.8
Synonyms:	
Formula:	C ₂₁ H ₂₆ ClN
Molecular weight:	327.9 g/mol

Assay	Result	Specification	
Related substances (HPLC)	Conform		
Residual solvent: acetone	< 5000 ppm	<= 5000 ppm	#
Loss on drying	0,10 %	<= 0,5 %	
Residual solvent: Methanol	< 3000 ppm	<= 3000 ppm	#
Sulphated ashes	0,00 %	<= 0,1 %	
Residual solvent: Dimethylformamide	< 880 ppm	<= 880 ppm	#
Assay	99,6 %	99,0 - 101,0 %	
Residual solvent: methylene chloride	< 600 ppm	<= 600 ppm	#
Elemental impurities	Conform	Test PhEur	#
Residual solvent: Acetonitrile	< 410 ppm	<= 410 ppm	#
Residual solvent: Petroleum ether	< 50 ppm	<= 50 ppm	#
Nitrosamine impurities	Conform	Test PhEur	#
Impurity B	< 0,05 %	<= 0,15 %	
Identification	Conform (A,B)		
Impurity E	< 0,05 %	<= 0,05 %	
Organoleptic properties	Conform	PhEur	
Unspecified Impurities	ND	<= 0,10 %	
Total impurities	< 0,05 %	<= 0,3 %	

Organoleptic characteristics: White or almost white powder. Very slightly or slightly soluble in water, freely soluble in anhydrous ethanol and in methanol, slightly soluble in acetone.

Conservation: In tightly closed containers. Protect from light.

Date of analysis: 21/10/2022

Judgement:
APPROVED

Responsible: C. Codina

Technical director: Montserrat Enrique

Manufacturer: F00436 VIJAYASRI ORGANICS PRIVATE LIMITED

Manufacturer batch: TER019G22

Product	Name	Capacity	Batch
1100150	TERBINAFINA CLORHIDRATO	10 g	224768-F-1
1100150	TERBINAFINA CLORHIDRATO	10 g	224768-F-2
1100151	TERBINAFINA CLORHIDRATO (INACTIVO)	25 g	224768-G-1
1100152	TERBINAFINA CLORHIDRATO	100 g	224768-J-1
1100152	TERBINAFINA CLORHIDRATO	100 g	224768-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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