



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 240662

Product:	BIFONAZOLE
Lot:	240662
Expiry date:	30/10/2027
Reference:	Cumple PhEur11.4
Synonyms:	
Formula:	C ₂₂ H ₁₈ N ₂
Molecular weight:	310,39 g/mol

Assay	Result	Specification	
Identification	Conform		
Organoleptic properties	Conform		
Related substances (HPLC)	Conform		
Loss on drying	0,02 %	<= 0,5 %	
Sulphated ashes	0,03 %	<= 0,1 %	
Assay	99,5 %	98,0-100,5%	
Impurity A	< 0,05 %	<= 0,2 %	
Impurity B	0,5 %	<= 0,5 %	
Impurity C	< 0,05 %	<= 0,2 %	
Impurity D	0,08 %	<= 0,5 %	
Impurity E	< 0,05 %	<= 0,15 %	
Unspecified Impurities	< 0,05 %	<= 0,10%	
Total impurities	0,6 %	<= 1,0 %	
Residual solvent: methylene chloride	ND	<= 600 ppm	#
Residual solvent: acetone	< 5000 ppm	<= 5000 ppm	#
Residual solvent: Isopropanol	< 5000 ppm	<= 5000 ppm	#
Residual solvent: Ethyl acetate	< 5000 ppm	<= 5000 ppm	#
Elemental impurities	Conform	Test PhEur	#
Nitrosamine impurities	Conform	Test PhEur	#

Organoleptic characteristics: White or almost white crystalline powder. Practically insoluble in water, sparingly soluble in anhydrous ethanol. It shows polymorphism

Conservation: In tightly closed containers. Protect from light.

Date of analysis: 17/05/2024

Judgement:
APPROVED

Responsible: M. Mesa

Technical director: Montserrat Enrique

Manufacturer: F00408 VITAL LABORATORIES PRIVATE LIMITED

Manufacturer batch: BFZ2211001

Product	Name	Capacity	Batch
1115352	BIFONAZOL	1 g	240662-D-1
1115352	BIFONAZOL	1 g	240662-D-2
1115352	BIFONAZOL	1 g	240662-D-3
1115352	BIFONAZOL	1 g	240662-D-4
1115353	BIFONAZOL	5 g	240662-E-1
1115353	BIFONAZOL	5 g	240662-E-2
1115353	BIFONAZOL	5 g	240662-E-3
1115353	BIFONAZOL	5 g	240662-E-4
1115355	BIFONAZOL	1 kg	240662-P-1
1115355	BIFONAZOL	1 kg	240662-P-2
1115355	BIFONAZOL	1 kg	240662-P-3

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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