



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 201947

Product:	BIFONAZOLE
Lot:	201947
Expiry date:	01/07/2025
Reference:	Cumple RFE5 - PhEur10.2
Synonyms:	
Formula:	C ₂₂ H ₁₈ N ₂
Molecular weight:	310,39 g/mol

Assay	Result	Specification	
Elemental impurities	Conform	Test PhEur	#
Residual solvent: Ethyl acetate	1177 ppm	<= 5000 ppm	#
Sulphated ashes	0,02 %	<= 0,1 %	
Residual solvent: methylene chloride	NDT	<= 600 ppm	#
Loss on drying	0,05 %	<= 0,5 %	
Total impurities	0,49 %	<= 1,0 %	
Residual solvent: Isopropanol	< LOQ	<= 5000 ppm	#
Assay	99,0 %	98,0-100,5%	
Residual solvent: acetone	< LOQ	<= 5000 ppm	#
Identification	Conform		
Impurity D	0,17 %	<= 0,5 %	
Impurity C	<= 0,05 %	<= 0,2 %	
Related substances (HPLC)	Conform		
Unspecified Impurities	0,06 %	<= 0,10%	
Organoleptic properties	Conform		
Impurity E	<= 0,05 %	<= 0,15 %	
Impurity B	0,26 %	<= 0,5 %	
Impurity A	<= 0,05 %	<= 0,2 %	

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: 11/12/2020

Judgement:
APPROVED

Responsible: M. Mesa

Technical director: Montserrat Enrique

Manufacturer: F00408 VITAL LABORATORIES PRIVATE LIMITED

Manufacturer batch: BFZ-P-2008001

Product	Name	Capacity	Batch
1115352	BIFONAZOL	1 g	201947-D-1
1115352	BIFONAZOL	1 g	201947-D-2
1115352	BIFONAZOL	1 g	201947-D-3
1115352	BIFONAZOL	1 g	201947-D-4
1115352	BIFONAZOL	1 g	201947-D-5
1115353	BIFONAZOL	5 g	201947-E-1
1115353	BIFONAZOL	5 g	201947-E-2
1115353	BIFONAZOL	5 g	201947-E-3
1115353	BIFONAZOL	5 g	201947-E-4
1115353	BIFONAZOL	5 g	201947-E-5
1115355	BIFONAZOL	1 kg	201947-P-2
1370228	BIFONAZOL (FLB) (INACTIVO)	1 kg	201947-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

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Date of edition: 04/05/2025