



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 215217

Product:	KETOCONAZOLE
Lot:	215217
Expiry date:	01/07/2026
Reference:	Cumple PhEur10.5
Synonyms:	
Formula:	C ₂₆ H ₂₈ Cl ₂ N ₄ O ₄
Molecular weight:	531,4 g/mol

Assay	Result	Specification	
Identification	Conform (B)	Test PhEur (A)	
Organoleptic properties	Conform	PhEur	
Appearance of 10% solution (CH ₂ Cl ₂)	Conform	PhEur	
Optical rotation	-0,008	(-0,1) - (+0,1)	
Related substances (HPLC)	Conform		
Loss on drying	0,03 %	<= 0,5 %	
Sulphated ashes	0,00 %	<= 0,1%	
ASSAY (anhydrous vehicle PFP)	99,4 %	99,0-101,0%	
Elemental impurities	Conform	Test PhEur	#
Impurity D	0,15 %	<= 0,2 %	
Unspecified Impurities	0,09 %	<= 0,10 %	
Total impurities	0,24 %	<= 0,3 %	
Residual solvent: Methanol	<=3000 ppm	<= 3000 ppm	#
Residual solvent: acetone	<=5000 ppm	<= 5000 ppm	#

Organoleptic characteristics: White or almost white powder. Practically insoluble in water, freely soluble in methylene chloride, soluble in methanol, sparingly soluble in ethanol (96 per cent).

Conservation: In airtight containers. Protect from light. Readily oxidable.

Date of analysis: 28/09/2021

Judgement:
APPROVED

Responsible: M. Mesa

Technical director: Montserrat Enrique

Manufacturer: F00001 AARTI DRUGS LTD.

Manufacturer batch: KET-12108345

Product	Name	Capacity	Batch
1155191	KETOCONAZOL (INACTIVO)	1 g	215217-D-1
1155192	KETOCONAZOL	5 g	215217-E-1
1155192	KETOCONAZOL	5 g	215217-E-2

1155193	KETOCONAZOL	10 g	215217-F-2
1155193	KETOCONAZOL	10 g	215217-F-3
1155194	KETOCONAZOL	25 g	215217-G-1
1155194	KETOCONAZOL	25 g	215217-G-2
1155196	KETOCONAZOL	100 g	215217-J-3
1200184	KETOCONAZOL	1 kg	215217-P-1
1200186	KETOCONAZOL	250 g	215217-N-1
1200186	KETOCONAZOL	250 g	215217-N-2
1370117	KETOCONAZOL (FLB)	100 g	215217-J-1
1370117	KETOCONAZOL (FLB)	100 g	215217-J-2
1370128	KETOCONAZOL (FLB)	10 g	215217-F-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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