



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 226115

Product:	KETOCONAZOLE
Lot:	226115
Expiry date:	31/01/2027
Reference:	Cumple PhEur10.8
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	-0.01	(-0,1) - (+0,1)	
Related substances (HPLC)	Conform		
Loss on drying	0,08 %	<= 0,5 %	
Sulphated ashes	0,04 %	<= 0,1%	
ASSAY (anhydrous vehicle PFP)	100,3 %	99,0-101,0%	
Elemental impurities	Conform	Test PhEur	#
Impurity D	<= 0,05 %	<= 0,2 %	
Unspecified Impurities	0,08 %	<= 0,10 %	
Total impurities	0,08 %	<= 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: 28/11/2022

Judgement:
APPROVED

Responsible: M. Mesa

Technical director: Montserrat Enrique

Manufacturer: F00001 AARTI DRUGS LTD.

Manufacturer batch: KET-12202067

Product	Name	Capacity	Batch
1155191	KETOCONAZOL (INACTIVO)	1 g	226115-D-1
1155192	KETOCONAZOL	5 g	226115-E-1
1155192	KETOCONAZOL	5 g	226115-E-2

1155192	KETOCONAZOL	5 g	226115-E-3
1155192	KETOCONAZOL	5 g	226115-E-4
1155193	KETOCONAZOL	10 g	226115-F-1
1155193	KETOCONAZOL	10 g	226115-F-4
1155193	KETOCONAZOL	10 g	226115-F-7
1155194	KETOCONAZOL	25 g	226115-G-1
1155194	KETOCONAZOL	25 g	226115-G-2
1155194	KETOCONAZOL	25 g	226115-G-3
1155196	KETOCONAZOL	100 g	226115-J-1
1155196	KETOCONAZOL	100 g	226115-J-4
1155196	KETOCONAZOL	100 g	226115-J-7
1200184	KETOCONAZOL	1 kg	226115-P-1
1200184	KETOCONAZOL	1 kg	226115-P-2
1200184	KETOCONAZOL	1 kg	226115-P-3
1200186	KETOCONAZOL	250 g	226115-N-1
1200186	KETOCONAZOL	250 g	226115-N-2
1200186	KETOCONAZOL	250 g	226115-N-3
1200186	KETOCONAZOL	250 g	226115-N-4
1200186	KETOCONAZOL	250 g	226115-N-5
1370117	KETOCONAZOL (FLB)	100 g	226115-J-2
1370117	KETOCONAZOL (FLB)	100 g	226115-J-3
1370117	KETOCONAZOL (FLB)	100 g	226115-J-5
1370117	KETOCONAZOL (FLB)	100 g	226115-J-6
1370128	KETOCONAZOL (FLB)	10 g	226115-F-2
1370128	KETOCONAZOL (FLB)	10 g	226115-F-3
1370128	KETOCONAZOL (FLB)	10 g	226115-F-5
1370128	KETOCONAZOL (FLB)	10 g	226115-F-6

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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