



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 251327

Product:	KETOCONAZOLE
Lot:	251327
Expiry date:	30/12/2029
Reference:	Cumple PhEur11.8
Synonyms:	
Formula:	C ₂₆ H ₂₈ Cl ₂ N ₄ O ₄
Molecular weight:	531,4 g/mol

Assay	Result	Specification	
Identification	Conform (A)		
Organoleptic properties	Conform	PhEur	
Appearance of solution	Conform	Test PhEur	
Optical rotation	(0,03)	(-0,10) - (+0,10)	
Related substances (HPLC)	Conform		
Loss on drying	0,00 %	<= 0,5 %	
Sulphated ashes	0,01 %	<= 0,1%	
Assay	99,3 %	99,0 -101,0 %	
Elemental impurities	Conform	Test PhEur	#
Nitrosamine impurities	Conform	Test PhEur	#
Impurity D	0,05 %	<= 0,2 %	
Unspecified Impurities	< 0,05 %	<= 0,10 %	
Total impurities	0,05 %	<= 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: 24/07/2025

Judgement:
APPROVED

Responsible: B. Chia

Technical director: Montserrat Enrique

Manufacturer: F00001 AARTI DRUGS LTD.

Manufacturer batch: KET-125010064

Product	Name	Capacity	Batch
1155192	KETOCONAZOL	5 g	251327-E-1
1155192	KETOCONAZOL	5 g	251327-E-2

1155193	KETOCONAZOL	10 g	251327-F-1
1155194	KETOCONAZOL	25 g	251327-G-1
1155196	KETOCONAZOL	100 g	251327-J-1
1200184	KETOCONAZOL	1 kg	251327-P-1
1200184	KETOCONAZOL	1 kg	251327-P-2
1200186	KETOCONAZOL	250 g	251327-N-1
1370117	KETOCONAZOL (FLB)	100 g	251327-J-2
1370128	KETOCONAZOL (FLB)	10 g	251327-F-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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