



## ANALYSIS CERTIFICATE

**Lot/Analysis/Analysis N°: 240909**

Product:	KETOCONAZOLE
Lot:	240909
Expiry date:	30/11/2028
Reference:	Cumple PhEur11.4
Synonyms:	
Formula:	C <sub>26</sub> H <sub>28</sub> Cl <sub>2</sub> N <sub>4</sub> O <sub>4</sub>
Molecular weight:	531,4 g/mol

Assay	Result	Specification	
Identification	Conform (A)		
Organoleptic properties	Conform	PhEur	
Appearance of solution	Conform	Test PhEur	
Optical rotation	+0,02	(-0,10) - (+0,10)	
Related substances (HPLC)	Conform		
Loss on drying	0,10 %	<= 0,5 %	
Sulphated ashes	0,04 %	<= 0,1%	
Assay	99,7 %	99,0 -101,0 %	
Elemental impurities	Conform	Test PhEur	#
Nitrosamine impurities	Conform	Test PhEur	#
Impurity D	0,07 %	<= 0,2 %	
Unspecified Impurities	0,07 %	<= 0,10 %	
Total impurities	0,21 %	<= 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: 21/05/2024

Judgement:  
APPROVED

Responsible: B.Chia

Technical director: Montserrat Enrique

Manufacturer: F00001 AARTI DRUGS LTD.

Manufacturer batch: KET-123120663

Product	Name	Capacity	Batch
1155192	KETOCONAZOL	5 g	240909-E-1
1155192	KETOCONAZOL	5 g	240909-E-2

1155192	KETOCONAZOL	5 g	240909-E-3
1155193	KETOCONAZOL	10 g	240909-F-1
1155193	KETOCONAZOL	10 g	240909-F-3
1155193	KETOCONAZOL	10 g	240909-F-5
1155194	KETOCONAZOL	25 g	240909-G-1
1155194	KETOCONAZOL	25 g	240909-G-2
1155194	KETOCONAZOL	25 g	240909-G-3
1155196	KETOCONAZOL	100 g	240909-J-1
1155196	KETOCONAZOL	100 g	240909-J-3
1155196	KETOCONAZOL	100 g	240909-J-5
1200184	KETOCONAZOL	1 kg	240909-P-1
1200184	KETOCONAZOL	1 kg	240909-P-2
1200186	KETOCONAZOL	250 g	240909-N-1
1200186	KETOCONAZOL	250 g	240909-N-2
1200186	KETOCONAZOL	250 g	240909-N-3
1370117	KETOCONAZOL (FLB)	100 g	240909-J-2
1370117	KETOCONAZOL (FLB)	100 g	240909-J-4
1370128	KETOCONAZOL (FLB)	10 g	240909-F-2
1370128	KETOCONAZOL (FLB)	10 g	240909-F-4

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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