

## Certificate of Analysis

**Product name:** **Ketoconazolum**

**Batch number / Weight:** **22J01-B03-221008 / 25 G**

**Analysed according to:** **Ph.Eur.10.8**

**Number of analysis / Inspection Code** **22J01-B03 / INS-22-8693**

**Reference Code / No.:** **V01415 / KET/12208450**

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white powder	Conform		
Identification B	Conform	Conform		
Appearance of solution	Clear / $\leq$ BY4	Conform		
Optical rotation	-0,10 - + 0,10	+0,033	°	
Related substances	Conform	Conform		
Impurity D	$\leq$ 0,2	0,09	%	
Unspecified impurities	$\leq$ 0,10	0,061	%	
Total impurities	$\leq$ 0,3	0,16	%	
Loss on drying	$\leq$ 0,5	0,06	%	
Sulphated ash	$\leq$ 0,1	0,01	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		
Residual solvents	CPMP/ICH/82 260/06	Conform		
Assay	99,0 - 101,0	99,82	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		
Residual solvents				
Acetone	not more than 3000 ppm	<5000	ppm	
Methanol	not more than 1500 ppm	<3000	ppm	

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Fagron Sp. z o.o.  
ul. Armii Krajowej 3  
32-540 Trzebinia, Poland  
e-mail:biuro@fagron.pl

fagron.pl

Fagron sp. z o.o.  
ul. Pasternik 26, 31-354 Kraków, Poland  
tel.: +48 12 3343 512  
e-mail: biuro@fagron.pl

All the manufacturing stages of this batch have been carried out in full compliance with the GMP requirements of the EU and with the national legal requirements.

Analysis performed by the authorized lab Fagron PL lab,CBMiA

Release:

Agnieszka Pszczółka

Qualified Person

15-12-2022

Expiration: 31-07-2027

Conclusion: APPROVED

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Fagron Sp. z o.o.  
ul. Armii Krajowej 3  
32-540 Trzebinia, Poland  
e-mail:biuro@fagron.pl