

Certificate of Analysis

Product name: Ketoconazolum
Batch number / Weight: 25I24-B07-016683 / 100 g
Producer / Producer Batch Number: Aarti Drugs Limited / KET/125080445
Analyzed according to: Ph.Eur.11.8
Number of Analysis / Certificate no.: 25I24-B07 / QO0024301

	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, crystalline powder	Conform		
Identification	A	Conform		
Appearance of solution	Clear and ≤BY4	Conform		
Optical rotation	(-0,10) - (+ 0,10)	+0,001	°	
Related substances	Conform	Conform		
Impurity D	≤ 0,2	0,08	%	
Unspecified impurities	≤ 0,10	< 0,05	%	
Total impurities	≤ 0,3	0,08	%	
Loss on drying	≤ 0,5	0,07	%	
Sulfated ash	≤ 0,1	0,00	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		DP
Residual solvents	CHMP/ICH/82260/2006	Conform		DP
TSE/BSE-statement:	EMA/410/01 guidance compliant – no contamination	Conform		DP
Assay	99,0 - 101,0	99,80	% m/m	

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 FSNE lab

Release:

17-11-2025
 Dominika Sottysik
 Qualified Person

Expiration: 31-7-2030

Conclusion: APPROVED

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