

Certificate of Analysis

Productname: Ketoconazolum
Number of analysis/Inspection Code: 1 / KEUR-182671B
Batchnumber: 18E28-B02-368779
Reference code / No.: 4178 / KET/11802071
Analysed according to: PH.EUR 9.4

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white powder	Conform		
Identification B	Conform	Conform		IR-spectrum
Appearance of solution	Clear / <=BY4	Conform		10%m/V in dichloormethaan
Optical rotation	-0,10 - + 0,10	-0,01	°	10%m/V in dichloormethaan
Related substances	Conform	Conform		HPLC
Total impurities	<=0,5	0,1	%	
Loss on drying	<= 0,5	0,1	%	105°C
Sulphated ash	<= 0,1	0,0	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CHMP/ICH/82260/2006	Conform		Data producer
Assay Ketoconazole	99,0 - 101,0	99,7	%m/m	Dried
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized laboratory Eurofins.

Release:
Wai Lung Chung
Pharmacist - Qualified Person

05/12/20

Expiration: 01-2023

Conclusion: APPROVED

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