

Certificate of Analysis

Productname: Miconazoli nitras micronisatum
Number of analysis/Inspection Code: 1 / KEUR-180022B
Batchnumber: 19J16-F02-366301
Reference code / No.: 4181 / 1950002545
Analysed according to: PH.EUR9.8+

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white powder	Conform		
Particle size	99%<25 µm / 90%<10 µm	Conform		
Identification A	178 - 184	183	°C	Melting point
Identification B	Conform	Conform		IR-spectrum
Appearance of solution	Clear <=Y7	Conform		1%m/V in methanol
Optical rotation	-0,10 - +0,10	+0,00	°	1%m/V MeOH
Related substances	Conform	Conform		HPLC
Impurity A	<=0,25	0,00	%	
Impurity B	<=0,25	0,00	%	
Impurity C	<=0,25	0,00	%	
Impurity D	<=0,25	0,00	%	
Impurity E	<=0,25	0,00	%	
Impurity F	<=0,25	<0,05	%	
Impurity G	<=0,25	0,00	%	
Unspecified impurities	<=0,10	<0,05	%	
Total impurities	<=0,5	0,0	%	
Loss on drying	<=0,5	0,1	%	2 h 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 Miconazole nitrate	99,0 - 101,0	100,5	%m/m	Dried
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized laboratory Pharma Cosmetic Polen.

Release:
 dr. M.J. Vincenten - van Maanen
 Pharmacist - Qualified Person

01/30/20

Expiration: 08-2024

Conclusion: APPROVED

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