

Certificate of Analysis

Product name: **Miconazoli nitras**

Batch number / Weight: **22F08-B02-213900 / 25 G**

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

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white powder	Conform		
Particle size	99%<25 µm / 90%<10 µm	Conform		
Identification A	178 - 184	Conform		
Identification B	Conform	Conform		
Appearance of solution	Clear <=Y7	Conform		
Optical rotation	-0,10 - +0,10	-0,005	°	
Related substances	Conform	Conform		
Unspecified impurities	<=0,10	<0,05		
Total impurities	<=0,5	0,00	%	
Loss on drying	<=0,5	0,03	%	
Sulphated ash	<=0,1	0,03	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay Miconazole nitrate	99,0 - 101,0	99,72	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer
Methanol		<3000	ppm	
Toluene		<890	ppm	

Analysis performed by the authorized lab.

Release:
Dominika Sołtysik
Qualified Person

07-07-2022

Expiration: 28-02-2027

Conclusion: APPROVED

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