

Certificate of Analysis

Product name: **Miconazoli nitras**
Batch number / Weight: **21E27-B07-217786 / 10 G**
Analysed according to: **Ph. Eur.**

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white powder	Conform		
Identification A	178 - 184	Conform	°C	
Identification B	Conform	Conform		
Appearance of solution	Clear <=Y7	Conform		
Optical rotation	-0,10 - +0,10	Conform	°	
Related substances	Conform	Conform		
Impurity A	<=0,25	<0,05	%	
Impurity B	<=0,25	<0,05	%	
Impurity C	<=0,25	<0,05	%	
Impurity D	<=0,25	<0,05	%	
Impurity E	<=0,25	<0,05	%	
Impurity F	<=0,25	<0,05	%	
Impurity G	<=0,25	<0,05	%	
Unspecified impurities	<=0,10	<0,05	%	
Total impurities	<=0,5	<0,05	%	
Loss on drying	<=0,5	0,04	%	
Sulphated ash	<=0,1	0,07	%	
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	100,4	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized lab.

Release:
 Ewelina Gadzinowska
 Qualified Person

09-12-2021

Expiration: 12-02-2026

Conclusion: APPROVED

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