

Certificate of Analysis

Product name: **Miconazoli nitras**
Batch number / Weight: **22F08-B02-223133 / 25 G**
Analysed according to: **Ph. Eur. 10.8**
Number of analysis / Inspection Code **22F08-B02 / INS-22-5176**
Reference Code / No.: **V01872 / MIMA2310**

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	<3000	ppm	
Toluene	<=890	<890	ppm	

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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 FAGRON PL lab

Release:

Ewelina Gadzinowska

Qualified Person

06-10-2022

Expiration: 28-02-2027

Conclusion: APPROVED

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