

Certificate of Analysis

Product name: **Econazole nitrate**

Batch number / Weight: **23F27-B01-230678 / 5 G**

Analysed according to: **Ph.Eur.11**

Number of analysis / Inspection Code **23F27-B01 / INS-23-6143**

Reference Code / No.: **/ API/ECN/221004**

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white powder	Conform		
Identification	Conform	Conform		
Related substances	Conform	Conform		
Impurity A	$\leq 0,2$	$< 0,05$	%	
Impurity B	$\leq 0,2$	$< 0,05$	%	
Impurity C	$\leq 0,2$	$< 0,05$	%	
Unspecified impurities	$\leq 0,10$	0,050	%	
Total impurities	$\leq 0,3$	0,10	%	
Loss on drying	$\leq 0,5$	0,01	%	
Sulfated ash	$\leq 0,1$	0,00	%	
Assay	99,0-101,0	100,40	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		
Residual solvents	CPMP/ICH/82 260/06	Conform		

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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

22-09-2023

Expiration: 30-09-2027

Conclusion: APPROVED

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