

Certificate of Analysis

Product name: **Minoxidilum**

Batch number / Weight: **23G05-B06-232273 / 100 G**

Analysed according to: **Ph.Eur.11.2**

Number of analysis / Inspection Code **23G05-B06 / INS-23-5439**

Reference Code / No.: **V01120 / 23004**

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, crystalline powder	Conform		
Identification	According to Ph. Eur.	Conform		
Identification B	Conform	Conform		
Solubility	According to Ph. Eur. Slightly soluble in water Soluble in methanol and in propylene glycol	Conform		
Related substances	Conform	Conform		
Impurity E	$\leq 0,2$	0,07	%	
Impurity B	$\leq 0,15$	0,000	%	
Unspecified impurities	$\leq 0,10$	$< 0,05$	%	
Total impurities	$\leq 0,3$	0,07	%	
Loss on drying	$\leq 0,5$	0,02	%	
Sulfated ash	$\leq 0,1$	0,01	%	
Assay Minoxidil	99,0 - 101,0 (dried substance)	100,44	%m/m	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer
TAMC	$\leq 10^3$	< 10	CFU/g	
TYMC	$\leq 10^2$	< 10	CFU/g	

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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,CBMiA

Release:
Dominika Soltysik
Qualified Person

18-09-2023

Expiration: 31-05-2028

Conclusion: APPROVED

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