Certificate of Analysis

Product name: Piroxicamum
Batch number / Weight: 23I19-B03-007966 / 10 g
Analyzed according to: Ph. Eur.11.7
Number of Analysis / Certificate no.: 23I19-B03 / QO0013915
Reference code / No.: V01409 / 2308913

	Requirement	Result	Unit	Standard remark
Appearance	White /slightly yellow, crystalline powder; it shows polymorphism	Conform		
IR-spectrum	Conform	Conform		
Related substances	Conform	Conform		
Impurity A	<=0,2	0,00	%	
Impurity B	<=0,2	0,00	%	
Impurity D	<=0,2	0,00	%	
Impurity J	<=0,2	0,00	%	
Impurity G	<=0,2	0,00	%	
Unspecified impurities	<=0,10	<0,05	%	
Total impurities	<=0,4	0,00	%	
Loss on drying	<=0,5	0,07	%	
Sulfated ash	<=0,1	0,02	%	
Assay	98,5 - 101,0	100,35	% m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		DP
Metallic residues	CHMP/ICH/353369/2013	Conform		DP
Residual solvents	CPMP/ICH/82 260/06	Conform		DP

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:

9-4-2025
Agnieszka Pszczółka
Qualified Person

Expiration: 10-7-2028
Conclusion: APPROVED

This document has been produced electronically from our quality system and is valid without signature.

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