Certificate of Analysis

Product name: **Xylometazolini hydrochloridum**

Batch number / Weight: **21K10-B04-215570 / 5 G**

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

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, crystalline powder	Conform		
Identification A	Conform	Conform		
Identification E	White	Conform		
Appearance of solution	Clear / <=Y6	Conform		
Acidity or alkalinity	Conform	Conform		
Related substances	Conform	Conform		
Impurity A	<=0,2	<0,05	%	
Unspecified impurities	<=0,10 each	Conform	%	
Total impurities	<=0,5	0,05	%	
Loss on drying	<=0,5	0,02	%	
Sulphated ash	<=0,1	0,05	%	
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay	99,0 - 101,0	100,77	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer
Metallic residues	CHMP/ICH/353369/2013	Conform		

Analysis performed by the authorized lab.

Release:
Agnieszka Pszczółka
Qualified Person

28-12-2021

Expiration: 22-06-2024

Conclusion: APPROVED

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Fagron sp. z o.o.
ul. Pasternik 26, 31-354 Kraków, Poland
tel.: +48 12 3343 512
e-mail: biuro@fagron.pl