Certificate of Analysis

Product name: **Xylometazolini hydrochloridum**

Batch number / Weight: **22G14-B02-220927 / 10 G**

Analysed according to: **Ph. Eur. 10.8**

Number of analysis / Inspection Code **22G14-B02 / INS-22-5935**

Reference Code / No.: **V00729 / 21312028**

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	0,1 ml NaOH		
Related substances	Conform	Conform		
Impurity A	<=0,2	<0,05	%	
Unspecified impurities	<=0,10 each	<0,05	%	
Total impurities	<=0,5	0,00	%	
Loss on drying	<=0,5	0,08	%	
Sulphated ash	<=0,1	0,03	%	
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay	99,0 - 101,0	100,97	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer
Metallic residues	CHMP/ICH/353369/2013	Conform		
Residual solvents				
2-Propanol	<= 5000	<5000	ppm	
Toluene	<= 890	<890	ppm	
Dimethylformamide	<= 880	<880	ppm	

fagron.pl

Fagron Sp. z o.o.
ul. Armii Krajowej 3
32-540 Trzebinia, Poland
e-mail:biuro@fagron.pl

fagron.pl

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

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

25-08-2022

Expiration: 02-08-2025

Conclusion: APPROVED

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

fagron.pl

Fagron Sp. z o.o.
ul. Armii Krajowej 3
32-540 Trzebinia, Poland
e-mail:biuro@fagron.pl