

## Certificate of Analysis

**Product name:** **Xylometazolini hydrochloridum**

**Batch number / Weight:** **22G14-B02-222242 / 5 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 / $\leq Y_6$	Conform		
Acidity or alkalinity	Conform	0,1 ml NaOH		
Related substances	Conform	Conform		
Impurity A	$\leq 0,2$	$< 0,05$	%	
Unspecified impurities	$\leq 0,10$ each	$< 0,05$	%	
Total impurities	$\leq 0,5$	0,00	%	
Loss on drying	$\leq 0,5$	0,08	%	
Sulphated ash	$\leq 0,1$	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	$\leq 5000$	$< 3000$	ppm	
Toluene	$\leq 890$	$< 890$	ppm	
Dimethylformamide	$\leq 880$	$< 880$	ppm	

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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

25-08-2022

Expiration: 02-08-2025

Conclusion: APPROVED

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