

Certificate of Analysis

Product name: **Xylometazolini hydrochloridum**
Batch number / Weight: **22C11-B05-221020 / 400 MG**
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 / $\leq Y_6$	Conform		
Acidity or alkalinity	Conform	0,05 ml NaO		
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	$\leq 0,5$	0,03	%	
Sulphated ash	$\leq 0,1$	0,01	%	
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay	99,0 - 101,0	99,55	%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	ppm	
Toluene		< 890	ppm	
Dimethylformamide	< 880 ppm	Conform	ppm	

Analysis performed by the authorized lab.

Release:
 Ewelina Gadzinowska
 Qualified Person

20-07-2022

Expiration: 06-08-2025

Conclusion: APPROVED

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