

Certificate of analysis



Article	4730	Xylometazolinhydrochlorid, API	
Synonym		Xylometazolini hydrochloridum	
Synonym		Xylometazoline hydrochloride, API	
Batch	23002949		
Specification	Ph.Eur.11.0		
Production date	07.2022	Retest date	07.2026

Test	Specification	Result	
Characters	According to specification	Complies	
Appearance	According to specification	Complies	
Solubility	According to specification	Complies	
Identification	According to specification	Complies	
IR spectrophotometry	According to specification	Complies	
E	According to specification	Complies	
Tests	According to specification	Complies	
Appearance of solution	According to specification	Complies	
Acidity or alkalinity	According to specification	Complies	
Related substances	According to specification	Complies	#
Impurity A	Max. 0.2 %	< 0.1 %	#
Each unspecified impurity	Max. 0.10 %	< 0.10 %	#
Total of all impurities	Max. 0.5 %	< 0.1 %	#
Loss on drying	Max. 0.5 %	0.0 %	
Sulphated ash	Max. 0.1 %	< 0.1 %	#
Assay	99.0 ... 101.0 %	100.2 %	#
Correction factor weighing (f, NRF)	1,000	1,000	
Complies specification		Yes	

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Production date	07.2022	Retest date	07.2026

Release date	28.11.2023	Released by	Frau Dr. Haßel, QP, LQK
Manufacturer	Siegfried PharmaChemikalien Minden GmbH		
Manufacturer batch	22272091		
Manufacturer street	Karlstrasse 15-39, 42-44		
Manufacturer city	32423 Minden		
Manufacturer country	Deutschland		

GMP-compliant production and testing of the active pharmaceutical ingredients

Results marked with # were taken from the manufacturer's certificate.

The batch 23002949 complies specification.

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