Certificate of analysis

Article	4730	Xylometazolinhydrochlorid, API
Synonym		Xylometazolini hydrochloridum
Synonym		Xylometazoline hydrochloride, API
Batch	22000302	
Specification	Ph.Eur.10.1	
Production date	06.2020	Retest date	06.2024

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 %	0,0 %
Each unspecified impurity	Max. 0,10 %	0,06 %
Total of all impurities	Max. 0,5 %	0,1 %
Loss on drying	Max. 0,5 %	0,0 %
Sulphated ash	Max. 0,1 %	0,0 %
Assay	99,0 ... 101,0 %	100,2 %
Correction factor weighing (f, NRF)		0,998
Complies specification		Yes

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Production date	06.2020	Retest date	06.2024

Release date	17.03.2022	Released by	Frau Dr. Haßel, QP, LQK
Manufacturer	Siegfried PharmaChemikalien Minden GmbH		
Manufacturer batch	20262072		
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 22000302 complies specification.

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