

Certificate of analysis



Article	4424	Naphazolinhydrochlorid, API	
Synonym		Naphazolini hydrochloridum	
Synonym		Naphazoline hydrochloride, API	
Batch	21000140		
Specification	Ph.Eur.10.0		
Production date	01.2020	Retest date	12.2024

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
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. 0,1 %	0,0 %
Each unspecified impurity	Max. 0,10 %	< 0,05 %
Total of all impurities	Max. 0,5 %	0,0 %
Loss on drying	Max. 0,5 %	0,0 %
Sulphated ash	Max. 0,1 %	0,0 %
Assay	99,0 ... 101,0 %	100,4 %
Correction factor weighing (f, NRF)		0,996
Complies specification		Yes

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Production date	01.2020	Retest date	12.2024

Release date	13.01.2021	Released by	Frau Dr. Haßel, QP, LQK
Manufacturer	M/s. Micro Labs Limited		
Manufacturer batch	NPZ3O20006		
Manufacturer street	Bommasandra Industrial Area, 4th Phase		
Manufacturer city	Anekal Taluk, Bengaluru 560 105		
Manufacturer country	Indien		

GMP-compliant production and testing of the active pharmaceutical ingredients

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

The batch 21000140 complies specification.

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