

Certificate of analysis



Article	4424	Naphazolinhydrochlorid, API	
Synonym		Naphazolini hydrochloridum	
Synonym		Naphazoline hydrochloride, API	
Batch	24001857		
Specification	Ph.Eur.11.0		
Production date	04.2024	Retest date	03.2029

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 %	100.2 %
Correction factor weighing (f, NRF)	1,000	1,000
Complies specification		Yes

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Production date	04.2024	Retest date	03.2029

Release date	05.12.2024	Released by	Frau Apoth. Dr. Schücker, QP
Manufacturer	M/s. Micro Labs Limited		
Manufacturer batch	NPZ3O24008		
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 24001857 complies specification.

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