

Certificate of analysis



Article	5059	Ambroxolhydrochlorid, API	
Synonym		Ambroxoli hydrochloridum	
Synonym		Ambroxol hydrochloride, API	
Batch	23003608		
Specification	Ph.Eur. 11.0		
Production date	01.2023	Retest date	01.2028

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
D	According to specification	Complies
Tests	According to specification	Complies
Appearance of solution	According to specification	Complies
pH-Value	4.5 ... 6.0	5.1
Related substances	According to specification	Complies
Each unspecified impurity	Max. 0.10 %	< 0.05 %
Total of all impurities	Max. 0.3 %	0.0 %
Loss on drying	Max. 0.5 %	0.0 %
Sulphated ash	Max. 0.1 %	0.0 %
Assay	99.0 ... 101.0 %	100.8 %
Correction factor weighing (f, NRF)	*****	1,000
Complies specification		Yes

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Release date	25.03.2024	Released by	Frau Apoth. Dr. Schücker, QP
Manufacturer	VEN Petrochem & Pharma (India) PVT LTD		
Manufacturer batch	AXL0763202301		
Manufacturer street	Plot N. 2903, 05, 07, 09, 10 & 2704		
Manufacturer city	396 155 Sarigaon, Valsad District, Sarigam, Gujarat		
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 23003608 complies specification.

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