

Certificate of analysis



Article	5182	Ciclopirox-Olamin, API	
Synonym		Ciclopirox olaminum	
Synonym		Ciclopirox olamine, API	
Batch	23000858		
Specification	Ph.Eur. 10.4		
Production date	01.2023	Retest date	01.2025

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
pH-Value	8,0 ... 9,0	8,7
Related substances	According to specification	Complies
Impurity A	Max. 0,5 %	0,0 %
Impurity B	Max. 0,5 %	0,0 %
Impurity C	Max. 0,5 %	0,0 %
Each unspecified impurity	Max. 0,10 %	< 0,05 %
Sum of all impurities except B	Max. 0,5 %	0,0 %
Loss on drying	Max. 1,5 %	0,1 %
Sulphated ash	Max. 0,1 %	< 0,1 %
Assay (Ciclopirox)	76,0 ... 78,5 %	77,9 %
Assay (2-aminoethanol)	22,2 ... 23,3 %	22,6 %
Correction factor weighing (f, NRF)		0,992
Complies specification		Yes

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Release date	20.07.2023	Released by	Frau Apoth. Dr. Schücker, QP
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Results marked with # were taken from the manufacturer's certificate.

The batch 23000858 complies specification.

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