

Certificate of analysis



Article	5182	Ciclopirox-Olamin, API	
Synonym		Ciclopirox olaminum	
Synonym		Ciclopirox olamine, API	
Batch	22003201		
Specification	Ph.Eur. 10.4		
Production date	07.2022	Retest date	07.2024

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
pH-Value	8,0 ... 9,0	8,6
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 %	77,8 %
Assay (2-aminoethanol)	22,2 ... 23,3 %	22,7 %
Correction factor weighing (f, NRF)		0,993
Complies specification		Yes

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Release date	01.12.2022	Released by	Frau Dr. Haßel, QP, LQK
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Results marked with # were taken from the manufacturer's certificate.

The batch 22003201 complies specification.

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