

Certificate of analysis



Article	5190	Clotrimazol, mikronisiert, API	
Synonym		Clotrimazolum	
Synonym		Clotrimazole, micronized, API	
Batch	21004116		
Specification	Ph.Eur.10.0		
Production date	09.2021	Retest date	09.2024

Test	Specification	Result
Characters	According to specification	Complies
Appearance	According to specification	Complies
Solubility	According to specification	Complies
Identification	According to specification	Complies
Melting point	141 ... 145 °C	144 °C
IR spectrophotometry	According to specification	Complies
Raman spectrophotometry	According to specification	Complies
Tests	According to specification	Complies
Related substances	According to specification	Complies
Impurity A	Max. 0,2 %	0,0 %
Impurity B	Max. 0,2 %	0,0 %
Impurity D	Max. 0,2 %	0,0 %
Impurity E	Max. 0,2 %	0,0 %
Impurity F	Max. 0,1 %	0,1 %
Each unspecified impurity	Max. 0,10 %	< 0,05 %
Total of all impurities	Max. 0,5 %	0,1 %
Loss on drying	Max. 0,5 %	0,2 %
Sulphated ash	Max. 0,1 %	0,0 %
Assay	98,5 ... 100,5 %	100,0 %
Correction factor weighing (f, NRF)		1,002
Complies specification		Yes

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Release date	24.01.2022	Released by	Frau Dr. Haßel, QP, LQK
Manufacturer	Halcyon Labs Pvt. Ltd.		
Manufacturer batch	HCZ17221		
Manufacturer street	Plot No. 409, Phase- IV, GIDC Estate,		
Manufacturer city	Naroda, Ahmedabad- 382 330		
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 21004116 complies specification.

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