

## Certificate of analysis



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Article	5190	Clotrimazol, mikronisiert, API	
Synonym		Clotrimazolum	
Synonym		Clotrimazole, micronized, API	
Batch	21004117		
Specification	Ph.Eur.10.0		
Production date	09.2021	Retest date	09.2024

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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 %	99,5 %
Correction factor weighing (f, NRF)		1,007
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	HCZ17421		
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 21004117 complies specification.

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