

Certificate of analysis



Article	2213	Dithranol, API	
Synonym		Dithranolum	
Synonym		Dithranol, API	
Batch	24000565		
Specification	Ph.Eur.11.0		
Production date	12.2022	Retest date	05.2026

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	178 ... 182 °C	179 °C
IR spectrophotometry	According to specification	Complies
Tests	According to specification	Complies
Related substances	According to specification	Complies
Impurity A	Max. 1 %	< 1 %
Impurity B	Max. 1 %	1 %
Impurity C	Max. 1 %	< 1 %
Impurity D	Max. 2.5 %	< 2.5 %
Total of all impurities	Max. 3.0 %	1.0 %
Chlorides	Max. 100 ppm	< 100 ppm
Loss on drying	Max. 0.5 %	0.2 %
Sulphated ash	Max. 0.1 %	0.0 %
Assay	98.5 ... 101.0 %	99.7 %
Correction factor weighing (f, NRF)	1,000	1,005
Complies specification		Yes

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Production date	12.2022	Retest date	05.2026

Release date	24.05.2024	Released by	Frau Dr. Haßel, QP, LQK
Manufacturer	Optimus Drugs (P) Ltd,		
Manufacturer batch	OP-DNL-C1-002/22		
Manufacturer street	Survey No. 239 & 240 Dothigudem		
Manufacturer city	Yadadri District-Bhuvanagiri - 508 284		
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 24000565 complies specification.

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