QUALITY CONTROL

Caesar & Loretz GmbH Herderstr. 31 40721 Hilden Phone: 02103/49940

Certificate of analysis



Article 2213 Dithranol, API

Synonym Dithranolum

Synonym Dithranol, API

Batch 24000565

Specification Ph.Eur.11.0

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 Related substances 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	Production date	12.2022	Retest date	05.2026
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 Loss on drying Max. 0.5 % 0.2 % Sulphated ash Max. 0.1 % 99.7 % Correction factor weighing (f, NRF) 1,000 1,005	Test		Specification	Result
Solubility Identification According to specification According to specification Complies Melting point According to specification Tests According to specification According to specification Complies Tests According to specification Complies Related substances According to specification Complies Impurity A Max. 1 % Impurity B Impurity C Max. 1 % Impurity D Max. 2.5 % Total of all impurities Max. 100 ppm Loss on drying Max. 0.5 % Sulphated ash Max. 0.1 % Max. 0.1 % Max. 0.0 % Assay Pa.5 101.0 % According to specification Complies Complies Complies Complies Complies Complies Complies Complies Complies Complies Complies Complies Complies Complies Complies Complies Complies Complies Complies Complies Complies Complies Complies Complies Complies Complies Complies Complies	Characters		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 % 99.7 % Correction factor weighing (f, NRF) 1,000 1,005	Appearance		According to specification	Complies
Melting point178 182 °C179 °CIR spectrophotometryAccording to specificationCompliesTestsAccording to specificationCompliesRelated substancesAccording to specificationCompliesImpurity AMax. 1 %< 1 %	Solubility		According to specification	Complies
IR spectrophotometry According to specification Complies According to specification Complies Related substances According to specification Complies Complies According to specification Complies Max. 1 % Impurity A Impurity B Impurity C Impurity D Max. 1 % Impurity D Max. 2.5 % Total of all impurities Max. 3.0 % Chlorides Max. 100 ppm Loss on drying Max. 0.5 % Sulphated ash Assay 98.5 101.0 % Correction factor weighing (f, NRF) According to specification Complies Complies Complies Complies According to specification Complies Complies According to specification Complies Complies According to specification Complies Complies And 1 % I % I % I % I % I % I % I %	Identification		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	Melting point		178 182 °C	179 °C
Related substances Impurity A Impurity B Impurity C Impurity D Max. 1 % Max. 1 % Max. 1 % Max. 1 % Impurity D Max. 2.5 % Total of all impurities Max. 100 ppm Loss on drying Max. 0.5 % Sulphated ash Max. 0.1 % Max. 0	IR spectrophotometry		According to specification	Complies
Impurity A Max. 1 % < 1 %	Tests		According to specification	Complies
Impurity B Max. 1 % 1 % Impurity C Max. 1 % < 1 %	Related substances		According to specification	Complies
Impurity C Max. 1 % < 1 %	Impurity A		Max. 1 %	< 1 %
Impurity D Max. 2.5 % < 2.5 %	Impurity B		Max. 1 %	1 %
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	Impurity C		Max. 1 %	< 1 %
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	Impurity D		Max. 2.5 %	< 2.5 %
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	Total of all impurities		Max. 3.0 %	1.0 %
Sulphated ash Max. 0.1 % 0.0 % Assay 98.5 101.0 % 99.7 % Correction factor weighing (f, NRF) 1,000 1,005	Chlorides		Max. 100 ppm	< 100 ppm
Assay 98.5 101.0 % 99.7 % Correction factor weighing (f, NRF) 1,000 1,005	Loss on drying		Max. 0.5 %	0.2 %
Correction factor weighing (f, NRF) 1,000 1,005	Sulphated ash		Max. 0.1 %	0.0 %
	Assay		98.5 101.0 %	99.7 %
Complies specification Yes	Correction factor weighing (f, NRF)		1,000	1,005
	Complies specification			Yes

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Article 2213 Dithranol, API

Synonym Dithranolum

Synonym Dithranol, API

Batch 24000565

Specification Ph.Eur.11.0

Production date 12.2022 Retest date 05.2026

Release date 24.05.2024 Released by Frau Dr. Haßel, QP,

Manufacturer LQK

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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