



S E R A T E C

DITHRANOL, EP - CERTIFICATE OF ANALYSIS

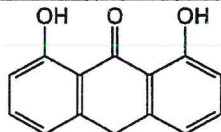
CERTIFIÉE CONFORME

À L'ORIGINAL

01.06.17

ASSURANCE QUALITE

J. SEBILLOT

			SPE n° CQ - 304 vs 09
C ₁₄ H ₁₀ O ₃	CAS RN [1143-38-0]	EINECS # 214-538-0	M.W. = 226.2 g.mol ⁻¹
1,8-dihydroxyanthracene – 9(10 H)- one 1,8-dihydroxy-9-anthrone			

BATCH N° DTHX - 099

TESTS	METHODS	SPECIFICATIONS	RESULTS
CHARACTERS	Visual examination	Yellow to brownish-yellow crystalline powder	Yellow crystalline powder
IDENTIFICATION			
A. Melting Point	EP, 2.2.60	178.0°C - 182.0°C	On going
B. Infra Red Spectrum	EP, 2.2.24	Conform to IR spectrum of Dithranol CRS	Conform to IR spectrum of Dithranol CRS
TESTS			
Chlorides	EP, 2.4.4	≤ 100 ppm	Complies
Loss on Drying	EP, 2.2.32	≤ 0.5%	0.1%
Sulphated Ash	EP, 2.4.14	≤ 0.1%	0.0%
Heavy metals	EP, 2.4.8, Method C	≤ 20 ppm	Complies
Related Substances	EP, 2.2.29 Method A	Imp. A or B or C: ≤ 1.0% Unknown imp.: ≤ 1.0%	A = 0.0 / B = 0.2% / C = 0.1% Unknown impurities = 0.0%
	EP, 2.2.29 Method B	Impurity D: ≤ 2.5%	0.2%
	Method A and B	Total impurities: ≤ 3.0%	0.5%
Residual Solvents	EP, 2.2.28	Methanol: ≤ 3000 ppm Xylenes: ≤ 2170 ppm Ethyl acetate: ≤ 5000 ppm	335 ppm ND 972 ppm
ASSAY	EP, 2.2.20	98.5% - 101.0% of C ₁₄ H ₁₀ O ₃ , calculated on the dried substance	100.1%

ND = Not Detected

Written by : S. GEB CZYNSKI	Reviewed by : S. GEORGIN
Date : 31/05/17 Visa : 861	Date : 31/05/17 Visa : 350

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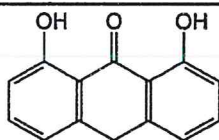


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DITHRANOL, EP - CERTIFICATE OF ANALYSIS

COPIE CERTIFIEE CONFORME
A L'ORIGINAL
LE : 01/06/2017
PAR L'ASSURANCE QUALITE

J. SEBILLOT

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TESTS	METHODS	SPECIFICATIONS	RESULTS
MICROBIAL LIMIT TESTS	USP <61> / Eur. Ph. 2.6.12 ACM Pharma	Total aerobic microbial count TAMC : NMT 1000 CFU/g Yeast and molds TYMC ⁽¹⁾ : NMT 100 CFU/g	On going

⁽¹⁾ Considering the intrinsic inhibitive nature of the product, we can presume that the impossibility to isolate the inoculated microorganism (Candida albicans) is imputable to the antimicrobial activity of the product.
LT = Less Than

MANUFACTURING DATE	December 2016
RETEST DATE	December 2018
ANALYSES	Date : 30 th May 2017 By : C. COUPEAU & S. MOREAU
COMPLIANT WITH SPECIFICATIONS	



Written by : S. GEBCZYNSKI	Reviewed by : S. GEORGIN
Date : 31/05/17 Visa : SGI	Date : 31/05/17 Visa : SGI

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