



COPIE CERTIFIEE CONFORME

A L'ORIGINAL

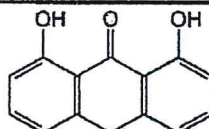
Le 30/11/16

PAR L'ASSURANCE QUALITE

JSC

SERATEC

DITHRANOL, EP - CERTIFICATE OF ANALYSIS

			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 - 089

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	180.6°C
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%	0.3%
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 = ND / B = 0.1% / C = 0.0% Unknown impurities = 0.0%
	EP, 2.2.29 Method B	Impurity D: ≤ 2.5%	0.2%
	Method A and B	Total impurities: ≤ 3.0%	0.4%
Residual Solvents	EP, 2.2.28	Methanol: ≤ 3000 ppm Xylenes: ≤ 2170 ppm Ethyl acetate: ≤ 5000 ppm	397 ppm ND 631 ppm
ASSAY	EP, 2.2.20	98.5% - 101.0% of $C_{14}H_{10}O_3$, calculated on the dried substance	99.7%

ND = Not Detected

Written by :	S. GEB CZYNSKI	Reviewed by :	
Date : 30/11/16	Visa : 	Date : 30/11/16	Visa : JSC

Seratec S.A.S.

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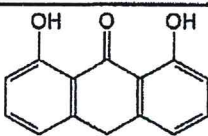


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S E R A T E C

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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	TAMC : LT 100 CFU/g TYMC : LT 100 CFU/g

⁽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.

MANUFACTURING DATE	November 2016		
RETEST DATE	November 2018		
ANALYSES	Date : 30 th November 2016		By : A. CAUDAN & S. MOREAU
COMPLIANT WITH SPECIFICATIONS			



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