



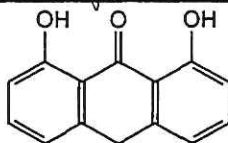
S E R A T E C

COPIE CERTIFIÉE CONFORME
À L'ORIGINAL
LE: 07/10/15
PAR L'ASSURANCE QUALITE

FAGRON IBÉRICA, S.A.U
Corresponde al lote de Fagron:

15J14-B11

DITHRANOL, EP - CERTIFICATE OF ANALYSIS



SPE H° CQ 304 vs 08

 $C_{14}H_{10}O_3$

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 - 080

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	179.0°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%	0.2%
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 = 0.1% / C = 0.0% Unknown impurities = 0.0%
	EP, 2.2.29 Method B	Impurity D: ≤ 2.5%	0.1%
	Method A and B	Total content: ≤ 3.0%	0.3%
Residual Solvents	EP, 2.2.28	Methanol: ≤ 3000 ppm Xylenes: ≤ 2170 ppm Ethyl acetate: ≤ 5000 ppm	543 ppm ND ND
ASSAY	EP, 2.2.20	98.5% - 101.0% of $C_{14}H_{10}O_3$, calculated on the dried basis	99.0%

ND = Not Detected

MANUFACTURING DATE	September 2015		
RETEST DATE	August 2017		
ANALYSES	Date : 2 nd September 2015		By : A. CAUDAN & C. COUPEAU
COMPLIANT WITH SPECIFICATIONS			
Written by : S. GEBICZYNSKI		Reviewed by : C. LE JAOEN	
Date : 07/10/15	Visa : 	Date : 07/10/15	Visa : 