

AGON
Pharma Pvt. Ltd.

CERTIFICATE OF ANALYSIS
DITHRANOL EP

NO	: 044	DATE	: 04-02-2022
NAME OF SAMPLE	: DITHRANOL EP	MFG. LICENSE NO	: PD/80
BATCH NO	: DT/044/21-22	DATE OF MFG	: 01-12-2021
QUANTITY	: 75.025 KGS	DATE OF EXPIRY	: 30-11-2026

Sr. No.	TEST	RESULTS	SPECIFICATION
1	Description	A Yellow microcrystalline Powder.	Yellow or brownish - yellow, crystalline powder.
2	Solubility	Test passes	Insoluble in water, soluble in methylene chloride, sparingly soluble in acetone, Slightly soluble in ethanol (96%). It dissolves in dilute solutions of alkali hydroxides.
3	Identification		
	A) Melting Point	181.2 °C	Limit 178 °C – 182 °C.
	B) I.R	Test Passes	(I.R) Comparison: Dithranol CRS.
	C) TLC	Test Passes	The principal spot obtained in the chromatogram of sample is similar in position, colour and size to the principal spot in the chromatogram obtained with reference solution a.
	D) Fluorescence	Test Passes	Examining in ultraviolet light at 365 nm, the solution shows a blue fluorescence.
4	Related Substances. Test -A Impurity A (Anthrone) Impurity B (Dantron) Impurity C (Dithranol Dimer)	0.051% 0.538% 0.409%	(Limit : max. 1.0 %) (Limit : max. 1.0 %) (Limit : max. 1.0 %)
	Test-B Impurity D (1 Hydroxy - 9- anthrone)	Below Detection Level	(Limit : max 2.5 %)
	Total (Test -A + Test-B)	0.998 %	(Limit : max 3.0 %)
5	Chloride	Complies	Not more than 100 ppm.
6	Loss on drying	0.37 %	Not more than 0.5 %
7	Sulfated Ash	0.02 %	Not more than 0.1%
8	Content of Dithranol , C ₁₄ H ₁₀ O ₃ Calculated on dried basis.	100.02 %	98.5 % to 101.0 %
9	Residual Solvent Methylene Chloride Isopropyl Alcohol	Test Passes (By G.C) 554.57 ppm Below Detection Level	Not more than 600 ppm. Not more than 5000 ppm.

Report: Above performed tests comply as per EP 10.0 specifications.

(The batch has been manufactured in full compliance with GMP requirements of the local Regulatory Authority)

Mr. M. R. Deshmane
Mr. M. R. Deshmane
Q. C. Incharge
Date :04/02/2022



Mr. S. M. Shaikh
Mr. S. M. Shaikh
Q. A. Incharge
Date : 04/02/2022

OFFICE : 3, Mulay Classic, Bhosale Nagar, Pune - 411 007. ☎ 020-25561648 Mob. 9422308928
FACTORY: Gat No. 837, Rly. Station Road, Yavat, Tal. Daund, Dist. Pune Pin-412214 (Maharashtra) ☎ 02119-274183
E-mail : agonpharma@hotmail.com / agonpharma@gmail.com **Website** : w.indiamart.com/agonpharma

Betr.: 1 kg. netto DITHRANOL EP 10.0, VAN ONZE PRINCIAAL AGON PHARMA LTD., INDIA, zoals geleverd met onze factuur No. 22029-2.031 d.d. 22.02.2022.



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