

AGON
Pharma Pvt. Ltd.

CERTIFICATE OF ANALYSIS

DITHRANOL EP

NO : 382
NAME OF SAMPLE : DITHRANOL EP
BATCH NO : DT/382/2012
QUANTITY : 100.0 KGS

DATE : 02.10.2012
MFG. LICENSE NO : PD/80
DATE OF MFG : 17.09.2012
DATE OF RE-TEST : 16.09.2017

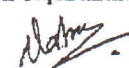
SR.NO.	TESTS	RESULTS	SPECIFICATIONS
1	Description	A yellow microcrystalline powder	Yellow or brownish - yellow, crystalline powder.
2	Solubility	Test passes	Practically insoluble in water, soluble in methylene chloride, sparingly soluble in acetone, slightly soluble in ethanol (96 %). It dissolves in dilute solutions of alkali hydroxides.
3	Identification	A) Melting Point : 179°C B) Test passes (I.R.) C) Test passes D) Test passes	(Limit : 178°C-182°C) (I.R.) Comparison : Dithranol CRS The principal spot in the chromatogram obtained in the test solution is similar in position, colour and size to the principal spot in the chromatogram obtained with reference solution (a). 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) Test-B Impurity D (1Hydroxy-9-anthrone) Total (Test A+Test B)	BDL 0.5528% BDL BDL 0.5528%	(Limit : max. 1.0%) (Limit : max. 1.0%) (Limit : max. 1.0%) (Limit : max. 2.5%) (Limit : max. 3.0%)
5	Chlorides	Complies	nmt 100 p.p.m.
6	Loss on drying	0.316%	nmt 0.5%
7	Sulphated ash	0.028%	nmt 0.1%
8	Content of Dithranol C ₁₄ H ₁₀ O ₃ . Calculated with reference to the dried substances	99.34%	98.5% to 101.0%
9	Residual Solvent Methylene Chloride Isopropyl Alcohol	Test passes (by G.C.) 14 ppm BDL	NMT 600 ppm NMT 5000 ppm

Report: Above performed test comply as per EP7 specification.

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


Q.C. Chemist
Date: 02.10.2012




Q.C. In-charge
Date: 02.10.2012

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DITHRANOL EP

NO : 382
NAME OF SAMPLE : DITHRANOL EP
BATCH NO : DT/382/2012
QUANTITY : 100.0 KGS

DATE : 17.09.2012
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DATE OF EXPIRY : 16.09.2017

SR.NO.	TESTS	RESULTS	SPECIFICATIONS
1	Description	A yellow microcrystalline powder	Yellow or brownish - yellow, crystalline powder.
2	Solubility	Test passes	Practically 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°C B) Test passes (LR.) C) Test passes D) Test passes	(Limit : 178°C-182°C) (LR) Comparison : Dithranol CRS The principal spot in the chromatogram obtained in the test solution is similar in position, colour and size to the principal spot in the chromatogram obtained with reference solution (a). 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) Test-B Impurity D (1Hydroxy-9-anthron) Total (Test A+Test B)	0.0670% 0.1968% BDL BDL 0.2638%	(Limit : max. 1.0%) (Limit : max. 1.0%) (Limit : max. 1.0%) (Limit : max. 2.5%) (Limit : max. 3.0%)
5	Chlorides	Complies	nmt 100 p.p.m.
6	Loss on drying	0.40%	nmt 0.5%
7	Sulphated ash	0.037%	nmt 0.1%
8	Content of Dithranol C14 H10 O3. Calculated with reference to the dried substances	99.42%	98.5% to 101.0%
9	Residual Solvent Methylene Chloride Isopropyl Alcohol	Test passes (by G.C.) BDL BDL	NMT 600 ppm NMT 5000 ppm

Report: Above performed test comply as per EP7 specification.

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

Q.C.Chemist

Date: 17.09.2012



Q.C. In-charge

Date: 17.09.2012

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