

#30090

asence Pharma Private Limited

Reg. Office : Asence House, Gorwa Road Vadodara 390 023.

Gujarat (INDIA) Phone : +91-265-2323179 . Website : www.asence.com

CIN Number : U24230 GJ2004 PTC045141

CERTIFICATE OF ANALYSIS

Name of Product : Crotamiton

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Batch No.: 23C36AN28

Date of Mfg. : Mar. - 2023

A.R.No. : FP_LA/029/22-23ACRO

Date of Expiry : Feb. - 2028

Sr. No.	TESTS	OBSERVATIONS	STANDARDS	Method Reference
1.	Appearance	Pale Yellow colour oily liquid.	Colourless or pale yellow, oily liquid. At low temperatures it may partly or completely solidify.	E.P.
2.	Solubility	Slightly soluble in water, miscible with ethanol (96 %).	Slightly soluble in water, miscible with ethanol (96 %).	E.P.
3.	Identification			
	UV Spectrum	Complies	Abs. Maxima 242 nm(Test A)	E.P.
	I.R. Spectrum	The infrared absorption spectrum of the sample is concordant with the spectrum of Crotamiton standard.	The infrared absorption spectrum of the sample should be concordant with the spectrum of Crotamiton standard. (Test B)	E.P. (2.2.24)
	TLC	The principal spot in the chromatogram obtained with the test solution is similar in position and size to the principal spot in the chromatogram obtained with the reference solution.	The principal spot in the chromatogram obtained with the test solution Should be similar in position and size to the principal spot in the chromatogram obtained with the reference solution.(Test C)	E.P. (2.2.27)
	Chemical Test	Complies	A brown colour is produced and a brown precipitate is formed on standing. (Test D)	E.P.
4.	Relative Density	1.009	Between 1.006 to 1.011	E.P. (2.2.5)
5.	Refractive index	1.541	Between 1.540 to 1.542	E.P. (2.2.6)
6.	Free amines	Complies	Not more than 500 ppm	E.P.
7.	Chlorides	Complies	Not more than 100 ppm	E.P.




Factory Address : Plot No.1408,1409 , G.I.D.C. , Ankleshwar-393002 . Dist. : Bharuch , Gujarat (INDIA)

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CERTIFICATE OF ANALYSIS**Name of Product :** Crotamiton**Page No. -** Page 2 of 2**Batch No.:** 23C36AN28**Date of Mfg. :** Mar. - 2023**A.R.No. :** FP_LA/029/22-23ACRO**Date of Expiry :** Feb. - 2028

Sr. No.	TESTS	OBSERVATIONS	STANDARDS	Method Reference
8.	Sulphated ash	0.06 %	Not more than 0.1 %	E.P. (2.2.14)
9.	Related substance By HPLC			
	Impurity – A	0.77 %	Not more than 3.0 %	E.P. (2.2.29)
	Unspecified impurities	0.08 %	Each impurity is Not more than 0.10 %	E.P. (2.2.29)
	Sum of impurity other than Imp-A	0.16 %	Not More Than 1.0 %	E.P. (2.2.29)
10.	Assay By HPLC			
	Z isomer	6.35 %	Not more than 15.0 %	E.P. (2.2.29)
	Sum of E and Z - isomer	99.08 %	Between 96.0 % and 102.0%	E.P. (2.2.29)
	Additional Test			
11.	Residual solvent By GC			
	Toluene	16 ppm	Not more than 890 ppm	In-house
	Benzene (As contaminant of Toluene)	Below detection limit	Not more than 2 ppm	In-house
Conclusion: The sample complies with EP 10.0 and In house specifications.				
Prepared By : Piyusha Jadhav		Checked By : Surekha Patil		Approved By : Sunil Pandya
Sign : 		Sign : 		Sign : 
Designation : Q.C.Chemist		Designation : Sr. Executive Q.C.		Designation : V.P.Quality
Date : 25/04/2023		Date : 25/04/2023		Date : 25/04/2023

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