

CROTAMITONUM 100 mL

Lot No.: 23G31-FRM30197

Authorisation:	1186R06102	Date Of Analysis:	13/06/2023
Analytical Reference:	Ph.Eur. [04/2023:1194]	Production Number:	290823
CNK:	4178-679	Expiry Date:	03/2028

ANALYTICAL TESTS

CHARACTERS	SPECIFICATION	RESULT
Appearance	Colourless or pale yellow, oily liquid.	Conform
Solubility	Slightly soluble in water, miscible with ethanol (96 per cent)	Conform
IDENTIFICATION	SPECIFICATION	RESULT
Infrared absorption spectrophotometry	The spectrum complies with the spectrum obtained with Crotamiton CRS	Conform
TESTS	SPECIFICATION	RESULT
Relative density	1.006 – 1.011	1.009
Refractive index	1.540 – 1.542	1.540
Free amines	≤ 500 ppm	< 500 ppm
Chlorides	≤ 100 ppm	< 100 ppm
Related substances		
Impurity A	≤ 3.0 %	1.2 %
Impurity B	≤ 0.5 %	Not detected
Unspecified impurities	≤ 0.10 %	Not detected
Sum of impurities other than A	≤ 1.0 %	Not detected
Sulfated ash	≤ 0.1 %	0.01 %
ASSAY	SPECIFICATION	RESULT
Sum of the (E)- and (Z)-isomers	96.0 % – 102.0 %	98.2 %
(Z)-isomer	≤ 15.0 %	4.9 %
Manufacturer identification code: S/GS/030		

CONCLUSION: COMPLIES

RESPONSIBLE PHARMACIST: