

Certificate of Analysis

Productname: Crotamitonum
Number of analysis/Inspection Code: 1 / KEUR-187118B
Batchnumber: 20J02-F01-374901
Reference code / No.: 3863 / C40-20080
Analysed according to: PH.EUR10.2

Tests	Requirement	Result	Unit	Standard remark
Appearance	Colourless or pale yellow, oily liquid	Conform Conform		
Identification B	Conform	Conform		IR-spectrum
Relative density	1,006 - 1,011	1,006		
Refractive index	1,540 - 1,542	1,542		
Free amines	<=500	Conform	ppm	
Chlorides	<=100	Conform	ppm	
Related substances	Conform	Conform		HPLC
Impurity A	<=3,0	0,8	%	
Unspecified impurities	<=0,10	0,05	%	
Sum of impurities other than A	<=1,0	0,1	%	
Sulphated ash	<=0,1	0,0	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CHMP/ICH/82260/2006	Conform		Data producer
Assay Crotamiton	96,0 - 102,0	98,7	%m/m	
Assay Z-isomer	<=15,0	1,7	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized laboratory Pharma Cosmetic Polen.

Release:
Paul Hofman
Pharmacist - Qualified Person

11/18/20

Expiration: 09-2025

Conclusion: APPROVED

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