

## Certificate of Analysis

**Productname:** Crotamitonum  
**Number of analysis/Inspection Code:** 1 / KEUR-183941B  
**Batchnumber:** 20B26-F02-371398  
**Reference code / No.:** 3863 / C40-20004  
**Analysed according to:** PH.EUR10.1

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	1,009		
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	0,9	%	
Unspecified impurities	<=0,10	<0,02	%	
Sum of impurities other than A	<=1,0	<1,0	%	
Sulphated ash	<=0,1	0,0	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CHMP/ICH/82260/2006	Conform		
Assay Crotamiton	96,0 - 102,0	99,1	%m/m	
Assay Z-isomer	<=15,0	2,1	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized laboratory Eurofins.

Release:  
Paul Hofman  
Pharmacist - Qualified Person

07/03/20

Expiration: 01-2025

Conclusion: APPROVED

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