

Certificate of Analysis

Productname: Crotamitonum
Number of analysis/Inspection Code: 1 / KEUR-179846B
Batchnumber: 18J08-B04-364805
Reference code / No.: 3863 / C40-18029
Analysed according to: PH.EUR 9.5

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	0,5	%	
Unspecified impurities	<=0,10	<0,10	%	
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	98,6	%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:
dr. M.J. Vincenten - van Maanen
Pharmacist - Qualified Person

01/28/20

Expiration: 04-2023

Conclusion: APPROVED

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