

Certificate of Analysis

Productname: **Crotamitonum**

Inspection No: I09311/1221/536
 Batchnumber: **20J02-F01-090497**
 Expiration date: 11.09.2025
 Analysed according to: ČL 2017, Ph.Eur.10.0
 Original Manuf. Date: 12.9.2020

Sample Unit: 1 x 1 g
 Batch Size: 35 x 100 g

Identification of producer: V00760
 Batch no. of vendor: C40-20080

	Requirement	Result	Unit	Standard remark	Insp. Site
CHARACTERS					
Appearance	Colourless or pale yellow, oily liquid.	Conform			Fagron CZ
Solubility	Conform	Conform			Fagron CZ
IDENTIFICATION					
Identification B	Conform	Conform		IR-spectrum	Fagron CZ
TESTS					
Relative density	1,006 - 1,011	1,006			Fagron PL
Refractive index	1,540 - 1,542	1,542			Fagron PL
Free amines	<=500	<500	ppm		Fagron PL
Chlorides	<=100	<100	ppm		Fagron PL
Related substances	Conform	Conform		HPLC	Fagron PL
Impurity A	<=3,0	0,79	%		Fagron PL
Unspecified impurities	<= 0,10	0,05	%		Fagron PL
Sum of impurities other than A	<= 1,0	0,05	%		Fagron PL
Sulfated ash	<=0,1	0,03	%		Fagron PL
Microbiology	Conform	Conform			Contract Lab
TAMC	<=2 x 10 ³	<10	CFU/g		Contract Lab
TYMC	<=2 x 10 ²	<10	CFU/g		Contract Lab
TSE/BSE	No contamination with TSE/BSE-risk materials.	Conform			Data Producer
Residual solvents	CPMP/ICH/82 260/2006	Conform			Data Producer
Metallic residues	ICH Q3D on elemental impurities	Conform			Data Producer
ASSAY					
Sum of the (E)- and (Z)-isomers	96,0 - 102,0	98,7	%	HPLC	Fagron PL
(Z)-isomer	<=15,0	1,67	%	HPLC	Fagron PL

Name Fagron a.s. (CZ)
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Performed by: Lucie Kubáňová DiS.
Responsible: Ing. Pavel Mišák, QC
MVDr. Zdenka Borská, QA
Date: 01.12.2021
Conclusion: APPROVED

This document has been produced electronically from our quality system and is valid without signature.

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