



Certificate of Analysis

Productname: **Crotamitonum**

Inspection No: J01648/0322/536
Batchnumber: **22A19-T02-092897**
Expiration date: 31.08.2026
Analysed according to: ČL 2017, Ph.Eur.10.0
Original Manuf. Date: 30.9.2021

Sample Unit: 1 x 1 g
Batch Size: 628 x 100 g

Identification of producer: V01726
Batch no. of vendor: 21J36AN07

	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	1,010			Fagron CZ
Refractive index	1,540 - 1,542	1,541			Fagron CZ
Free amines	<=500	<500	ppm		Fagron CZ
Chlorides	<=100	<100	ppm		Fagron CZ
Related substances	Conform	Conform		HPLC	Contract Lab
Impurity A	<=3,0	<3,0	%		Contract Lab
Unspecified impurities	<= 0,10	<0,02	%		Contract Lab
Sum of impurities other than A	<= 1,0	<0,02	%		Contract Lab
Sulfated ash	<=0,1	0,0	%		Fagron CZ
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	ICH Q3C	Conform			Data Producer
Metallic residues	ICH Q3D	Conform			Data Producer
ASSAY					
Sum of the (E)- and (Z)-isomers	96,0 - 102,0	97,0	%	HPLC	Contract Lab
(Z)-isomer	<=15,0	6,9	%	HPLC	Contract Lab

Quality: API

Name	Fagron a.s. (CZ)	Address	Holická 1098/31m, Olomouc	Phone No.	+420585222590
	Kontrolní laboratoř č. 536	Post Code	779 00	Fax No.	+420 585 226 521

Performed by: Ing. Petra Drábková

Responsible: Ing. Pavel Mišák, QC
MVDr. Zdenka Borská, QA

Date: 14.03.2022

Conclusion: **APPROVED**

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