



Certificate of Analysis

Productname: **Crotamitonum**

Inspection No: K06541/0423/536
Batchnumber: **23F07-T04-101673**
Expiration date: 30.04.2028
Analysed according to: Ph.Eur.11.1
Original Manuf. Date: 31.5.2023

Sample Unit: 1 x 1 g
Batch Size: 672 x 100 g

Identification of producer: V01726
Batch no. of vendor: 23E36N04

	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	1,011			Fagron CZ
Refractive index	1,540 - 1,542	1,540			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
Impurity B	<=0,5	<0,05	%		Contract Lab
Unspecified impurities	<=0,10	<0,05	%		Contract Lab
Sum of impurities other than A	<=1,0	<0,05	%		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	98,1	%	HPLC	Contract Lab
(Z)-isomer	<=15,0	5,5	%	HPLC	Contract Lab

Quality: API

Name	Fagron a.s. (CZ)	Address	Holická 1098/31m, Olomouc	Phone No.	+420585222590
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Performed by: Ludmila Stochlebová

Responsible: Mgr. Barbora Vránová, QC
MVDr. Zdenka Borská, QP

Date: 20.09.2023

Conclusion: **APPROVED**

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