



## Certificate of Analysis

**Productname:** **Crotamitonum**

**Inspection No:** K06542/1023/536  
**Batchnumber:** **23H22-T03-106119**  
**Expiration date:** 30.06.2028  
**Analysed according to:** Ph.Eur.11.1  
**Original Manuf. Date:** 31.7.2023

**Sample Unit:** 1 x 1 g  
**Batch Size:** 181 x 100 g

**Identification of producer:** V01726  
**Batch no. of vendor:** 23G36AN09

	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 <sup>3</sup>	<10	CFU/g		Contract Lab
TYMC	<=2 x 10 <sup>2</sup>	<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	98,8	%	HPLC	Contract Lab
(Z)-isomer	<=15,0	7,4	%	HPLC	Contract Lab

Quality: API

<b>Name</b>	Fagron a.s. (CZ)	<b>Address</b>	Holická 1098/31m, Olomouc	<b>Phone No.</b>	+420585222590
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**Performed by:** Bc. Andrea Šmídová

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

**Date:** 20.09.2023

**Conclusion:** **APPROVED**

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