Fagron
personalizing medicine

Certificate of Analysis

Productname: **Crotamitonum**

Inspection No: I09325/1221/536
Batchnumber: **21J20-T03-090499**
Expiration date: 27.11.2025
Analysed according to: ČL 2017, Ph.Eur.10.0
Original Manuf. Date: 28.11.2020

Sample Unit: 0 x
Batch Size: 84 x 100 ml

Identification of producer: V01628
Batch no. of vendor: C40-20097

	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	1,542			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	<0,10	%		Contract Lab
Sum of impurities other than A	<= 1,0	<1,0	%		Contract Lab
Sulfated ash	<=0,1	0	%		Fagron CZ
Microbiology	Conform	Conform			Contract Lab
TAMC	<=2 x 103	<10	CFU/g		Contract Lab
TYMC	<=2 x 102	<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	99,1	%	HPLC	Contract Lab
(Z)-isomer	<=15,0	1,8	%	HPLC	Contract Lab

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The product conforms to ČL 2017, Ph.Eur.10.0.

Performed by: Lucie Kubáňová DiS.

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

Date: 13.12.2021

Conclusion: **I certify that the above-mentioned batch of pharmaceutical raw material has been manufactured and tested in accordance with the requirements of Marketing Authorization (License) and requirements of Good Manufacturing Practice.**

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

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