Fagron
personalizing medicine

Certificate of Analysis

Productname: **Macrogollaurylether 9**

Inspection No: I08532/1121/536
Batchnumber: **21I16-T04-092174**
Expiration date: 11.05.2023
Analysed according to: ČL 2017-Dopl.2020,Ph.Eur.10.0
Original Manuf. Date: 21.5.2021

Sample Unit: 0 x
Batch Size: 17 x 1 kg

Identification of producer: V01485
Batch no. of vendor: 21-0820

	Requirement	Result	Unit	Standard remark	Insp. Site
CHARACTERS					
Appearance	(Almost) white,unctuous,hydroscopic mass, melting at 24°C into a colourless or yellowish, viscous liquid.	Conform			Fagron CZ
Solubility	Conform	Conform			Fagron CZ
IDENTIFICATION					
Identification A	90 - 100	96		Hydroxyl value	Fagron CZ
Identification B	<=2,0	0,12		Iodine value	Fagron CZ
Identification C	<=3,0	0,28		Saponification value	Fagron CZ
Identification D	Conform	Conform		Precipitate	Fagron CZ
Identification F	Conform	Conform		Gas chromatography	Contract Lab
TESTS					
Appearance of solution	<=BY5	Conform			Fagron CZ
Alkalinity	<=0,5	<0,5	ml	0.1 M HCl	Fagron CZ
Acid value	<=1,0	0,14			Fagron CZ
Hydroxyl value	90 - 100	96			Fagron CZ
Iodine value	<=2,0	0,12			Fagron CZ
Saponification value	<=3,0	0,28			Fagron CZ
Ethylene oxide	<=1	<0,4	µg/g		Contract Lab
Dioxane	<=10	<2,5	µg/g	GC	Contract Lab
Water	<=3,0	0,11	%	Karl Fischer	Fagron CZ
Sulfated ash	<=0,2	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

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

The product conforms to ČL 2017-Dopl.2020,Ph.Eur.10.0.

Performed by:	Lucie Kubáňová DiS.
Responsible:	Ing. Pavel Mišák, QC MVDr. Zdenka Borská, QA
Date:	02.11.2021
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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