

Certificate of Analysis

Productname: **Macrogollaurylether 9**
Inspection No: I08523/1021/536
Batchnumber: **21116-T04-092170**
Expiration date: 11.05.2023
Analysed according to: ČL 2017-Dopl.2020,Ph.Eur.10.0
Original Manuf. Date: 21.5.2021

Sample Unit: 1 x 10 g
Batch Size: 1 821 x 10 g

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

	Requirement	Result	Unit	Standard remark	Insp. Site
CHARACTERS					
Appearance	(Almost) white, unctuous, hygroscopic 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 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	CPMP/ICH/82 260/2006	Conform			Data Producer
Metallic residues	ICH Q3D on elemental impurities	Conform			Data Producer

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

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: 03.11.2021



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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