

Certificate of Analysis

Productname: **Macrogollaurylether 9**

Inspection No: I06337/0821/536

Batchnumber: **20D20-T99-090484**

Expiration date: 03.02.2023

Analysed according to: ČL 2017-Dopl.2020,Ph.Eur.10.0

Original Manuf. Date: 14.2.2020

Sample Unit: 1 x 10 g

Batch Size: 1 825 x 10 g

Identification of producer: V01485

Batch no. of vendor: 20D20-T12-085761

	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	91		Hydroxyl value	Fagron CZ
Identification B	≤2,0	0,44		Iodine value	Fagron CZ
Identification C	≤3,0	1,1		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	0,40			Fagron CZ
Hydroxyl value	90 - 100	91			Fagron CZ
Iodine value	≤2,0	0,44			Fagron CZ
Saponification value	≤3,0	1,1			Fagron CZ
Ethylene oxide	≤1	<0,4	µg/g		Contract Lab
Dioxane	≤10	<2,5	µg/g	GC	Contract Lab
Water	≤3,0	0,22	%	Karl Fischer	Fagron CZ
Sulfated ash	≤0,2	0,08	%		Fagron CZ
Microbiology	Conform	Conform			Contract Lab
TAMC	≤2 x 10 ³	Conform	CFU/g		Contract Lab
TYMC	≤2 x 10 ²	Conform	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

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Performed by: Bc. Andrea Šmídová
Responsible: Ing. Pavel Mišák, QC
PharmDr. Ivana Urbánková, QA
Date: 11.08.2021
Conclusion: **APPROVED**



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