



Certificate of Analysis

Productname: **Macrogollaurylether 9**

Inspection No: I02901/0421/536
Batchnumber: **20D20-T12-085764**
Expiration date: 03.02.2022
Analysed according to: Ph.Eur.10.0
Original Manuf. Date: 14.2.2020

Sample Unit: 0 x
Batch Size: 400 x 25 g

Identification of producer: V01485
Batch no. of vendor: 20-0212

	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	93		Hydroxyl value	Fagron CZ
Identification B	≤2,0	0,25		Iodine value	Fagron CZ
Identification C	≤3,0	0,58		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	0,1	ml	0.1 M HCl	Fagron CZ
Acid value	≤1,0	0,17			Fagron CZ
Hydroxyl value	90 - 100	93			Fagron CZ
Iodine value	≤2,0	0,25			Fagron CZ
Saponification value	≤3,0	0,58			Fagron CZ
Ethylenoxide	≤1	<0,4	µg/g		Contract Lab
Dioxane	≤10	<4	µg/g		Contract Lab
Water	≤3,0	0,043	%	Karl Fischer	Fagron CZ
Sulfated ash	≤0,2	0,0	%		Fagron CZ
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: Lucie Kubáňová DiS.

Responsible: Ing. Mgr. Kateřina Jokešová, QC
PharmDr. Ivana Urbánková, QA

Date: 28.04.2021

Conclusion: APPROVED

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