



Certificate of Analysis

Productname: Macrogolglyc. oleates

Inspection No: K07732/1023/536

Batchnumber: 23H16-T03-106115

Expiration date: 31.03.2026

Analysed according to: ČL 2017-Dopl.2018, Ph.Eur. 11.0

Original Manuf. Date: 31.3.2023

Sample Unit: 1 x 20 ml

Batch Size: 100 x 250 ml

Identification of producer: V00752

Batch no. of vendor: 194677

	Requirement	Result	Unit	Standard remark	Insp. Site
CHARACTERS					
Appearance	Amber oily liquid, which may give rise to a deposit after prolonged periods at 20 °C.	Conform			Fagron CZ
Solubility	Conform	Conform			Fagron CZ
Relative density	About 0,95	0,95			Fagron CZ
Refractive index	About 1,47	1,47			Fagron CZ
Viscosity	About 35	35	mPa.s	40 °C	Fagron CZ
IDENTIFICATION					
Identification A	Conform	Conform		TLC	Fagron CZ
Identification B	45 - 65	51		Hydroxyl value	Fagron CZ
Identification C	150 - 170	161		Saponification value	Fagron CZ
Identification D	Conform	Conform		Composition of fatty acids	Contract Lab
TESTS					
Acid value	<=2,0	0,43			Fagron CZ
Hydroxyl value	45 - 65	51			Fagron CZ
Iodine value	75 - 95	85			Fagron CZ
Peroxide value	<=12,0	5,41			Fagron CZ
Saponification value	150 -170	161			Fagron CZ
Alkaline impurities	<=1,0	0,0	ml	0,01 mol/l HCl	Fagron CZ
Free glycerol	<=3,0	0,12	%	0,1 mol/l Na2S2O3	Fagron CZ
Composition of fatty acids	Conform	Conform		GC	Contract Lab
Palmitic acid	4,0 - 9,0	5,1	%		Contract Lab
Stearic acid	<=6,0	3,2	%		Contract Lab
Oleic acid	58,0 - 80,0	62,6	%		Contract Lab
Linoleic acid	15,0 - 35,0	26,7	%		Contract Lab
Linolenic acid	<=2,0	0,1	%		Contract Lab
Arachidic acid	<=2,0	0,4	%		Contract Lab
Eicosenoic acid	<=2,0	0,2	%		Contract Lab
Ethylene oxide	<=1	<0,3	ppm	GC	Contract Lab
Dioxane	<=10	<5,0	ppm	GC	Contract Lab
Water (Karl Fischer)	<=1,0	0,029	%		Fagron CZ
Total ash	<=0,1	0,0	%		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

Name Fagron a.s. (CZ)
Kontrolní laboratoř č. 536

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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

Quality: Excipient

Performed by: Bc. Andrea Šmídová

Responsible: Mgr. Zdeňka Šinclová, QC
MVDr. Zdenka Borská, QP

Date: 18.10.2023

Conclusion: **APPROVED**

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