

Certificate of Analysis

Productname: Macrogolglyc. oleates

Inspection No: I08064/1021/536
Batchnumber: 21H31-T01-086615
Expiration date: 30.03.2024
Analysed according to: ČL 2017, Dopl. 2018, Ph. Eur. 10.0
Original Manuf. Date: 31.3.2021

Sample Unit: 1 x 20 ml
Batch Size: 42 x 250 ml

Identification of producer: V00752
Batch no. of vendor: 184544

	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	Conform			Fagron CZ
Refractive index	About 1,47	Conform			Fagron CZ
Viscosity	About 35	Conform	mPa.s	40 °C	Fagron CZ
IDENTIFICATION					
Identification A	Conform	Conform		TLC	Fagron CZ
Identification B	45 - 65	57		Hydroxyl value	Fagron CZ
Identification C	150 - 170	167		Saponification value	Fagron CZ
Identification D	Conform	Conform		Composition of fatty acids	Contract Lab
TESTS					
Acid value	<=2,0	0,73			Fagron CZ
Hydroxyl value	45 - 65	57			Fagron CZ
Iodine value	75 - 95	83			Fagron CZ
Peroxide value	<=12,0	0,0948			Fagron CZ
Saponification value	150 -170	167			Fagron CZ
Alkaline impurities	<=1,0	0,3	ml	0,01 mol/l HCl	Fagron CZ
Free glycerol	<=3,0	0,17	%	0,1 mol/l Na2S2O3	Fagron CZ
Composition of fatty acids	Conform	Conform		GC	Contract Lab
Palmitic acid	4,0 - 9,0	4,8	%		Contract Lab
Stearic acid	<=6,0	3,2	%		Contract Lab
Oleic acid	58,0 - 80,0	67,6	%		Contract Lab
Linoleic acid	15,0 - 35,0	22,3	%		Contract Lab
Linolenic acid	<=2,0	<0,1	%		Contract Lab
Arachidic acid	<=2,0	0,3	%		Contract Lab
Eicosenoic acid	<=2,0	0,2	%		Contract Lab
Ethylene oxide	<=1	<0,2	µg/g	GC	Contract Lab
Dioxane	<=10	<2,5	µg/g	GC	Contract Lab
Water (Karl Fischer)	<=1,0	0,022	%		Fagron CZ
Total ash	<=0,1	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)
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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

Performed by: Lucie Kubáňová DiS.

Responsible: Ing. Pavel Mišák, QC
PharmDr. Ivana Urbánková, QA

Date: 27.10.2021

Conclusion: **APPROVED**

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