



Certificate of Analysis

Productname: Polysorbatum 80

Inspection No: J01517/0222/536

Batchnumber: 21L27-T05-091783

Expiration date: 30.11.2023

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

Original Manuf. Date: 12.11.2021

Sample Unit: 1 x 10 ml

Batch Size: 387 x 100 ml

Identification of producer: V01687

Batch no. of vendor: 1/2530306

	Requirement	Result	Unit	Standard remark	Insp. Site
CHARACTERS					
Appearance	Oily, colourless or brownish-yellow, clear. or slightly opalescent liquid.	Conform			Fagron CZ
Solubility	Conform	Conform			Fagron CZ
Relative density	About 1,10	1,08			Fagron CZ
Viscosity	About 400	400	mPa.s	25 °C	Fagron CZ
IDENTIFICATION					
Identification A	Conform	Conform		IR-spectrum	Fagron CZ
Identification D	Conform	Conform		Composition of fatty acids	Contract Lab
TESTS					
Acid value	<=2,0	0,24			Fagron CZ
Hydroxyl value	65 - 80	65			Fagron CZ
Peroxide value	<=10,0	0,815			Fagron CZ
Saponification value	45 - 55	50			Fagron CZ
Composition of fatty acids	Conform	Conform		GC	Contract Lab
Myristic acid	<=5,0	0,1	%		Contract Lab
Palmitic acid	<=16,0	16,0	%		Contract Lab
Palmitoleic acid	<=8,0	1,1	%		Contract Lab
Stearic acid	<=6,0	3,8	%		Contract Lab
Oleic acid	>=58,0	74,2	%		Contract Lab
Linoleic acid	<=18,0	0,5	%		Contract Lab
Linolenic acid	<=4,0	0,1	%		Contract Lab
Ethylene oxide	<=1	<0,3	µg/g	GC	Contract Lab
Dioxane	<=10	<3,5	µg/g	GC	Contract Lab
Water	<=3,0	2,4	%	Karl Fischer	Fagron CZ
Total ash	<=0,25	0,0	%		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

Quality: Excipient

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

Performed by: Ludmila Stochlebová

Responsible: Ing. Pavel Mišák, QC
MVDr. Zdenka Borská, QA

Date: 14.03.2022

Conclusion: **APPROVED**

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