

Certificate of Analysis

Productname: **Polysorbatum 80**

Inspection No: I09703/1221/536
 Batchnumber: **21K09-T06-092530**
 Expiration date: 31.10.2023
 Analysed according to: ČL 2017-Dopl.2020,Ph.Eur.10.0
 Original Manuf. Date: 12.10.2021

Sample Unit: 1 x 10 ml
 Batch Size: 845 x 100 ml

Identification of producer: V01596
 Batch no. of vendor: 1/2524786

	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	Conform			Fagron CZ
Viscosity	About 400	Conform	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	0,2			Fagron CZ
Hydroxyl value	65 - 80	80			Fagron CZ
Peroxide value	<=10,0	0,0			Fagron CZ
Saponification value	45 - 55	47			Fagron CZ
Composition of fatty acids	Conform	Conform		GC	Contract Lab
Myristic acid	<=5,0	0,2	%		Contract Lab
Palmitic acid	<=16,0	15,8	%		Contract Lab
Palmitoleic acid	<=8,0	0,9	%		Contract Lab
Stearic acid	<=6,0	3,7	%		Contract Lab
Oleic acid	>=58,0	73,8	%		Contract Lab
Linoleic acid	<=18,0	0,4	%		Contract Lab
Linolenic acid	<=4,0	<0,1	%		Contract Lab
Ethylene oxide	<=1	<0,2	µg/g	GC	Contract Lab
Dioxane	<=10	<2,5	µg/g	GC	Contract Lab
Water	<=3,0	2,5	%	Karl Fischer	Fagron CZ
Total ash	<=0,25	0,00	%		Fagron CZ
Microbiology	Conform	Conform			Contract Lab
TAMC	<=2 x 103	Conform	CFU/g		Contract Lab
TYMC	<=2 x 102	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

Name	Fagron a.s. (CZ)	Address	Holická 1098/31m, Olomouc	Phone No.	+420585222590
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Performed by: Mgr. Zdeňka Šinclová

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

Date: 08.12.2021

Conclusion: **APPROVED**

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