



Certificate of Analysis

Productname: Polysorbatum 80

Inspection No: K05688/0823/536
Batchnumber: 22L16-T01-104768
Expiration date: 30.06.2025
Analysed according to: Ph.Eur.11.2
Original Manuf. Date: 29.6.2022

Sample Unit: 1 x 10 ml
Batch Size: 1,064 x 100 ml

Identification of producer: V01687
Batch no. of vendor: 1/2544304

	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	1,10			Fagron CZ
Viscosity	About 400	Asi 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	0,21			Fagron CZ
Hydroxyl value	65 - 80	70			Fagron CZ
Peroxide value	<=10,0	0,456			Fagron CZ
Saponification value	45 - 55	49			Fagron CZ
Composition of fatty acids	Conform	Conform		GC	Contract Lab
Myristic acid	<=5,0	0,1	%		Contract Lab
Palmitic acid	<=16,0	14,0	%		Contract Lab
Palmitoleic acid	<=8,0	0,8	%		Contract Lab
Stearic acid	<=6,0	3,7	%		Contract Lab
Oleic acid	>=58,0	75,6	%		Contract Lab
Linoleic acid	<=18,0	0,5	%		Contract Lab
Linolenic acid	<=4,0	<0,05	%		Contract Lab
Ethylene oxide	<=1	<0,3	ppm	GC	Contract Lab
Dioxane	<=10	<3,5	ppm	GC	Contract Lab
Water	<=3,0	2,5	%	Karl Fischer	Fagron CZ
Total ash	<=0,25	0,11	%		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
TSE/BSE	No contamination with TSE/BSE-risk materials.	Conform			Data Producer
Residual solvents	ICH Q3C	Conform			Data Producer
Metallic residues	ICH Q3D	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 Burianová

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

Date: 23.08.2023

Conclusion: **APPROVED**

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