



Certificate of Analysis

Productname: Propylenglycolum

Inspection No: K09210/0124/536
Batchnumber: 21J19-T25-109513
Expiration date: 31.07.2026
Analysed according to: ČL 2017, Ph.Eur.10.0
Original Manuf. Date: 1.7.2021

Sample Unit: 1 x 50 ml
Batch Size: 91 x 250 ml

Identification of producer: V01486
Batch no. of vendor: K53587978

	Requirement	Result	Unit	Standard remark	Insp. Site
CHARACTERS					
Appearance	A viscous, clear, colourless, hygroscopic liquid.	Conform			Fagron CZ
Solubility	Conform	Conform			Fagron CZ
IDENTIFICATION					
Identification A	1,035 - 1,040	1,038		Relative density	Fagron CZ
Identification B	1,431 - 1,433	1,432		Refraction index	Fagron CZ
Identification C	184 - 189	184	°C	Boiling point	Fagron CZ
Identification D	121 - 128	122	°C	Melting temperature of crystals	Fagron CZ
TESTS					
Appearance	Clear / colourless	Conform			Fagron CZ
Relative density	1,035 - 1,040	1,038			Fagron CZ
Refractive index	1,431 - 1,433	1,432			Fagron CZ
Acidity	<=0,05	0,02	ml	0,1 mol/l NaOH	Fagron CZ
Oxidising substances	<=0,2	0,2	ml	0,05 mol/l Na ₂ S ₂ O ₃	Fagron CZ
Reducing substances	Conform	Conform			Fagron CZ
Water (Karl Fischer)	<=0,2	0,04	%		Fagron CZ
Sulfated ash	<=0,01	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, QP

Date: 08.12.2023

Conclusion: **APPROVED**

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